

[patrol uplc process analysis system]



TAKE CONTROL
OF YOUR BOTTOM LINE

Waters
THE SCIENCE OF WHAT'S POSSIBLE.®

A quality process comes first

**Developing, understanding, monitoring,
and controlling it just got faster and easier.**



*PATROL UPLC Process
Analysis System.*

UPLC and the framework for critical decisions.

Process development laboratories are being challenged to modernize scientific processes that ensure final product quality and improve process yields. One of the critical components is process analytical technology (PAT), where timely quantitative measurements are taken throughout production to measure Critical Quality Attributes (CQA).

With Waters[®] in-process decisions can rely on streaming CQA feedback. Real-time, chromatographic-quality analysis for in-process samples is now accessible with industry-proven UltraPerformance LC[®] (UPLC[®]) Technology, available with the PATROL UPLC[®] Process Analysis System.

Waters UPLC Technology has already changed the capabilities of discovery, development, and quality control laboratories, delivering better analytical data at up to 10X higher throughput levels.

Now, for the first time, you can bring automation and UPLC together for direct online connection to your process or sample with Real-TIME LC™ from the PATROL UPLC Process Analysis System.

The PATROL UPLC Process Analysis System can detect and quantify all the analytes in complex, multiple-component in-process samples, as well as final product at the point of production. With PATROL UPLC, you'll work with real-time information that provides a greater understanding of the efficiency and quality of your processes, so you can be more confident in decisions about your product.

QUALITY

Best-in-class analyses designed specifically for in-process analysis

The PATROL UPLC Process Analysis System delivers simultaneous qualitative and quantitative information that combine to make it the ultimate decision-making technology. And, powered by the best in LC separation technology – holistically-designed instrumentation that maximizes the performance of small-particle chromatography – PATROL UPLC gives you the real-time results you need to dynamically adjust and control your process.

CONTROL

Continuous system uptime

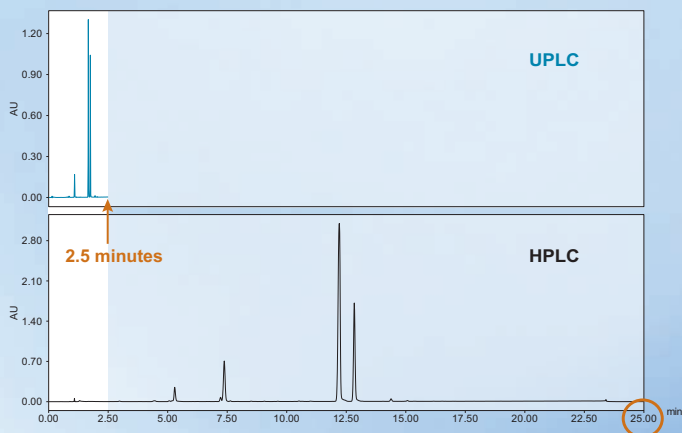
The PATROL UPLC Process Analysis System provides continuous operational uptime, with on-board diagnostics and remote access from any location to give you confidence that your process is under control and within design space. Connections INSIGHT® Remote Services provides 24-hour remote monitoring of the system's performance to ensure each component, module, and the entire system is running at peak efficiency. Connections INSIGHT also provides predictive alerts when system intervention will be needed. So, you'll know that the PATROL UPLC Process Analysis System guarding your process is always in control.

EFFICIENCY

From live data to historical trends, use the right information at the right time

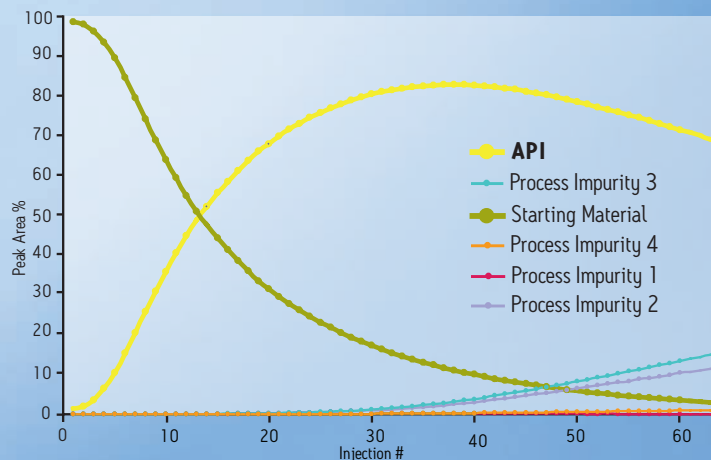
PATROL UPLC is controlled by Empower® Software, the market-leading data solution that QC and development labs depend on to manage GMP and 21 CFR Part 11 compliance. Empower Software automates the analysis of samples, comparing operational conditions to your pre-set parameters to ensure that every step of the process is under control. Results are continually collected, archived, and stored by the versatile NuGenesis® SDMS platform, which maintains data in a format that meets your reporting requirements. From statistical modeling to regulatory recordkeeping, the information you need is always available.

Better understand your PROCESS.



With its broad linear dynamic range and superior selectivity and sensitivity, only UPLC can rapidly quantitate major components of complex mixtures and low-level impurities in a single rapid analysis.

Better understand your PRODUCT.



Mapping the progress of an API and its impurities in a reaction vessel with the PATROL UPLC Process Analysis System provides a better understanding of the reaction's progress, so you can optimize product yield and purity.



BRAND GUARDIAN

In the world marketplace, your reputation is built on quality. When UPLC is used in your process development, it provides you with the confidence to ensure that your product – from biopharmaceuticals, to cosmetics, to beverages, to fine chemicals, to natural products – will stand up to its promise of quality. This translates directly to product success and consumer confidence.

Bringing Quality by Design to life

Today's process development and manufacturing priorities are built on following an efficient process that leads to the consistent production of a quality product. In an effort to reduce costs and improve profit margins, you need to continuously look for improvement within your processes. Waters has partnered closely with our customers to understand how our pioneering UPLC Technology can be used to support Quality by Design (QbD) principles.

We recognize that our customers can reap tremendous benefits by implementing a QbD strategy that is supported by forward-looking process analytical technology that:

- Enhances the scientific foundation of product review.
- Improves the overall product development lifecycle, ensuring that the system is efficient, agile, and flexible.
- Increases efficiencies and helps reduce costs based on less product variability and less waste.
- Builds a stronger scientific knowledge base for all products and better overall interaction between regulatory bodies and industry partners.



The ACQUITY UPLC® Process Sample Manager is the heart of the PATROL UPLC Process Analysis System, drawing and analyzing samples directly from batch reactors, flow reactors, bioreactors, or even purification columns.

THE PROMISE OF PATROL UPLC

With the PATROL UPLC Process Analysis System, you can rely on results that improve operational efficiency, deliver quantifiable ROI, and increase profits.

Increases:

- Process recoveries and yields
- Brand integrity due to quality improvements and faster delivery
- Consumer satisfaction
- Process understanding

Reduces:

- Process cycle times
- Process and product variability
- Product rework
- Bottlenecks



PATROL UPLC's intuitive touch-screen interface.

What UPLC Technology means for your processes.

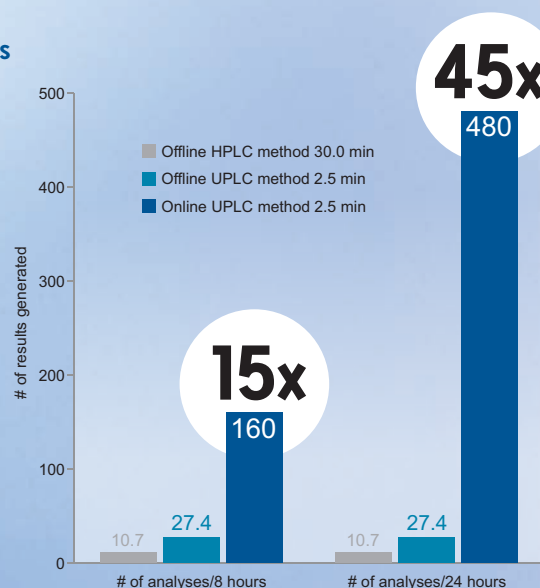
The spectroscopic technology used in many process development laboratories today provides real-time identity information about processes; however, it lacks the ability to simultaneously monitor multiple components at different levels and does not provide the quantitative analysis, sensitivity, linearity/dynamic range, and resolution that UPLC provides.

And, UPLC provides a fast and easy-to-use method that generates real-time data, filling the gap where the slower HPLC technique has traditionally come up short as the online and automated analytical tool desired by process chemists.



PATROL UPLC enables greater speed and efficiency for significant time savings

TASKS, IN MINUTES	OFFLINE HPLC IN QC	ATLINE PATROL UPLC	ONLINE PATROL UPLC
Extract sample	20	20	1
Deliver and log in sample to QC	30 to 60	1	0
Sample preparation	30 to 90	1	1
Chromatographic analysis	90 to 240	8	8
Interpret, review, approve, and sign-off data	60 to 120	0	0
Information entered to DCS/LIMS	10	0	0
TOTAL TIME	4 TO 9 HOURS	30 MINUTES	10 MINUTES



The analytical cornerstone for confident process development

Automated or walk-up sample entry – it's easy to run.

- Fully automated operation or accessed via an intuitive touch-screen interface, for simplified walk-up and single press-button interaction.
- Analytical procedures are fully automated from sample to results, allowing more agile decisions to move your production process forward.
- Designed for direct closed-loop feedback to a distributed control system (DCS) or laboratory information management system (LIMS).

Designed and engineered for continuous operation.

- Powered by proven UPLC Technology. From system and sample thermal management, to multi-buffer and multi-column management, to data processing and reporting, the functionality of each module of the PATROL UPLC Process Analysis System has been purposefully integrated to deliver optimal performance.
- Waters' best-in-class columns assure consistency of your results with batch-to-batch and column-to-column reproducibility.
- Engineered to enable fast and simple replacement of modular components for reduced downtime when maintenance is required.

On-board diagnostics improve uptime and reliability.

- Incorporates automated and comprehensive diagnostics tools with Connections INSIGHT Remote Services, which monitors the operational parameters of the system, and provides alerts if its performance is outside set user limits.
- The system provides predictive maintenance recommendations via automated visual, email, and mobile device alerts, so you can plan for downtime to minimize impact to your production line.
- Our proven commitment to best-in-class support services, technical knowledge, and quick resolution of system issues helps you protect and enhance the value of your investment in Waters technologies.

Real-time decision engine.

- PATROL UPLC reduces 60+ minute cycle times to less than 5 minutes, enabling real-time process feedback.
- With its broad linear dynamic range and excellent selectivity and sensitivity, only UPLC is able to rapidly quantitate major components of complex mixtures and low-level impurities in a single analysis.
- UPLC significantly increases throughput while simultaneously reducing solvent use without compromising analytical results.
- Using UPLC Technology in the process development space allows the use of consistent methodology, enabling data correlation to the entire product life cycle.

Flexibility and versatility.

- Allows you to use analytical technology throughout your process, with models available for online, atline, and offline analysis.
- With UPLC-optimized detectors and a portfolio of more than 100 UPLC columns, the system provides the versatility to support your application needs.
- Compliant-ready Empower Software provides a customer-proven QbD solution for automated workflows, from instrument control to peak integration.
- Data is automatically archived for efficient recordkeeping using the NuGenesis SDMS informatics platform. Archived data can readily be retrieved and used for regulatory support, trending analysis, and to review process changes over long periods of time.

Security features for controlled substance samples.

- Designed with security measures in place to ensure appropriate access and to track chain-of-custody compliance.
- Access-restricted door on the ACQUITY UPLC PSM, requiring a security code to insert or remove a sample.
- Complete traceability of and access to precious or controlled samples can be restricted to authorized users through Empower CDS.
- Optional, locking metal cabinet available for added security.



TYPICAL
PROCESS

9 steps

ACQUITY
UPLC PSM

4 steps

A typical offline sample analysis sequence can be reduced from nine distinct steps to four through the automated sample logging, dilution, analysis, and reporting functions embedded within the ACQUITY UPLC PSM and Empower CDS.

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Brazil 55 11 4134 3788
Canada 1 800 252 4752
China 86 21 6156 2666
Czech Republic 420 2 617 11384
Denmark 45 46 59 8080
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Germany 49 6196 400 600
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Hungary 36 1 350 5086
India 91 080 49292200 03
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Korea 82 2 6300 9200
Mexico 52 55 52 00 1860
The Netherlands 31 76 508 7200
Norway 47 6 384 6050
Poland 48 22 101 5900
Portugal 351 21 893 61 77
Puerto Rico 1 787 747 8445
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Switzerland 41 56 676 7000
Taiwan 886 2 2501 9928
UK 44 208 238 6100
US 1 800 252 4752

Waters Corporation
34 Maple Street
Milford, MA 01757 U.S.A.
T: 508 478 2000
F: 508 872 1990
www.waters.com

www.waters.com/patrol

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