BioAccord™ SYSTEM

Simplicity in every analysis.
Power in every insight.

POWERFUL | EASY TO USE | RELIABLE | COMPLIANCE-READY

Waters™

Your go-to platform for biopharmaceutical product attribute and process analysis.

1 Introduction

2 waters_connect Ecosystem

3 Usability and Reliability

4 Proteins and Peptides

5 Nucleic Acids and Delivery Vehicles

6 Bioprocess Monitoring

7 Configure Your System

The BioAccord LC-MS System: Where **Simplicity** meets **Power**

Simplicity of operation combined with a purposefully designed hardware and informatics platform provides users of all levels of LC-MS experience the **Power** to understand their product and process and confidently measure their control.

Reduce system downtime and improve separation quality with compatible MaxPeak™ Premier Systems and Columns.

Align with your sustainability goals with environmental impact metrics. Look for labels in 2025.

Achieve data integrity and regulatory compliance goals with a compliance-ready platform and our Global Services Team.

Enable new and experienced users with support from the Waters Global Services team to deploy the BioAccord System and support biopharmaceutical workflows.

Integrated Informatics Workflows from Characterization to QC Release

The waters_connect™ informatics ecosystem provides the flexibility to deploy LC-MS systems for product and process analysis, attribute monitoring, and product release. Compliance-ready biopharmaceutical applications streamline and automate data acquisition, processing, review, and reporting.

Characterization | Attribute Monitoring | Routine/QC Release

Attribute Characterization LC-MS platforms

Xevo™ MRT

Xevo™ G3 QTof MS

Users/Client PC(s)

waters_connect™

Network Server
Managed Data Scientific Library
Compliance Tools

Peptide MAM | UNIFI™ | INTACT Mass | MAP Sequence | CONFIRM Sequence | Bioprocess Monitor

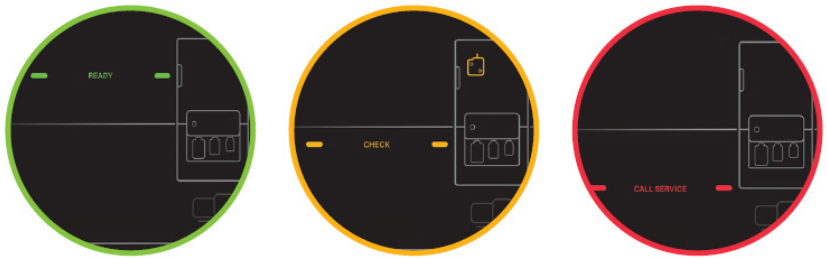
Attribute Analysis LC-MS systems

BioAccord LC-MS System

LC Optical System(s) and Client PC

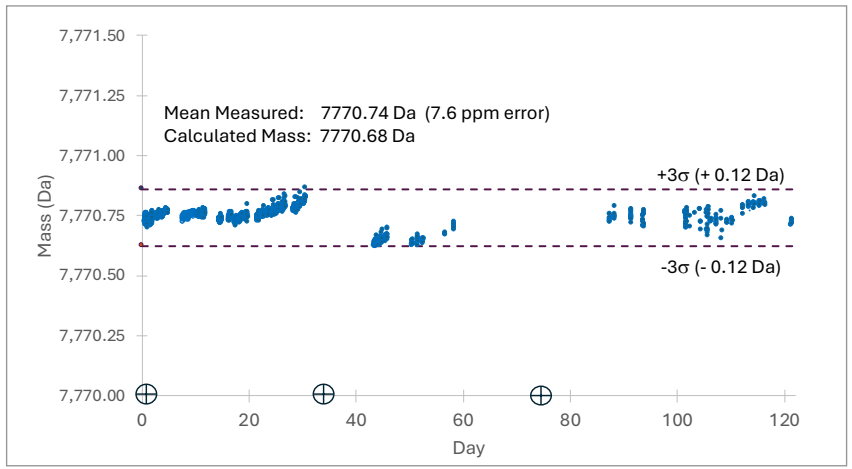
Designed for Usability and Reliability

LC-MS complexity has traditionally restricted the technology to central labs and experienced users. The BioAccord LC-MS System has been designed to provide robust operation and communicate system readiness to produce high quality biopharmaceutical data.



System is ready to use | *Check the ionization source* | *Call your Service Engineer*

Commercial calibration and system check standards support automated system setup and regular system verification checks to ensure proper operation. Detailed feedback on the front panel guides a user to quickly resolve detected issues.



BioAccord System robustness was evaluated using ~2000 intact IP-RP-LCMS analyses of a ~7.8 kDa PS 25-mer oligonucleotide (GEM91) over the course of 120 days of system operation. Data analysis was automated using the waters_connect INTACT Mass Application, and instrument setup-calibration (Cross hair Circles) was conducted on Days 1, 35 and 75. Average mass error of 7.6 ppm from the calculated mass was observed, and 3 sigma control limits (99.7% of data) were calculated at 0.12 Da.

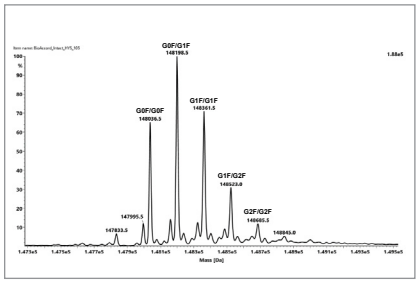
"The ease of use and system robustness enables less-expert users to perform LC-MS tasks, providing greater productivity for advanced analytical strategies such as Multi-Attribute Monitoring (MAM)"

Arnaud Delobel, R&D and Innovation Director, Quality Assistance

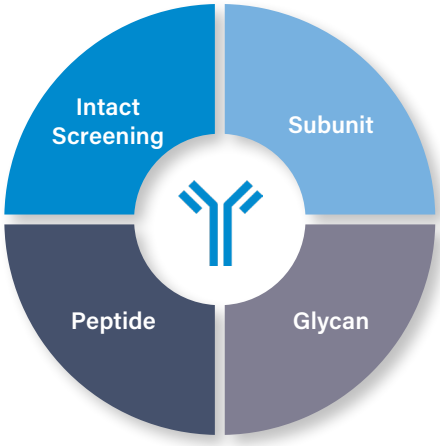
WATCH TESTIMONIAL

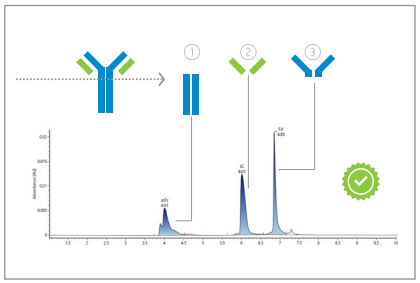
The BioAccord System for Protein-based Therapeutics and Vaccines

Accessible attribute analysis for protein & peptide therapeutics, from discovery screening to commercial manufacture.

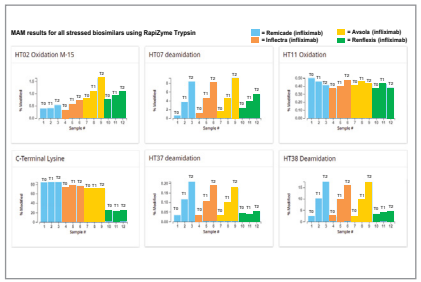


- Protein Identity and Glycovariants
- Bioconjugation Ratios
- Denatured and Native analysis

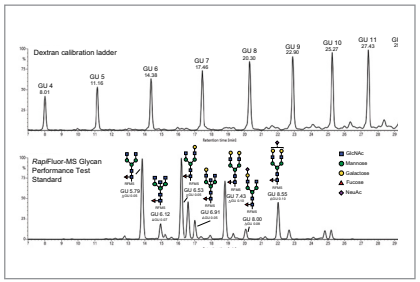




- Subunit Identity and Variation
- Localization of Modifications
- Glycovariant Profiles

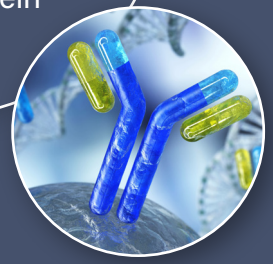


- LC-MS^E Peptide Mapping for Attribute Definition
- Peptide MAM for Attribute Monitoring



- Released N-glycan profiling using *RapiFluor*-MS™, 2AA, 2-AB, or your preferred label

mAb
Multispecific
Bioconjugate
Peptide
Fusion Protein



"The BioAccord System has accelerated our native analysis of proteins, increasing throughput threefold. An increase in mass range expands our ability to investigate AOCs, mAbs aggregates, multi-specific mAbs, and oligomer therapeutic proteins, enabling us to support increasingly complex therapeutics"

Dr. Oscar Hernandez Alba, BioOrganic Mass Spectrometry Laboratory (LSMBO), IPHC, CNRS, Strasbourg University

Complete workflows from sample prep to automated data analysis

Unparalleled application-specific consumables, automation, and system-check standards for optimal performance and reproducibility

Purposely designed compliance-ready informatics with intuitive application workflows

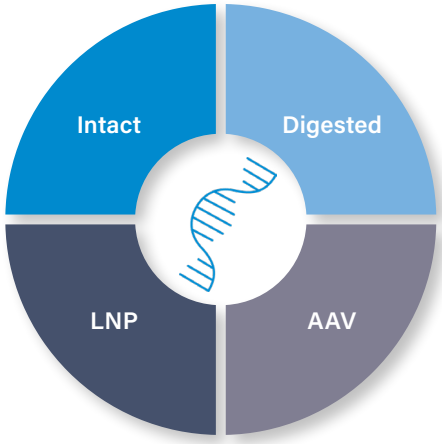
waters_connect™

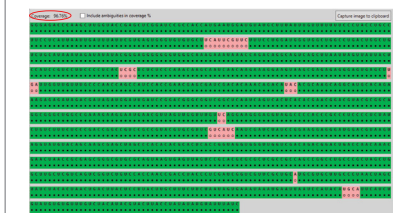
UNIFI™ | INTACT Mass | Peptide MAM

The BioAccord System for Nucleic acid-based therapeutics and vaccines

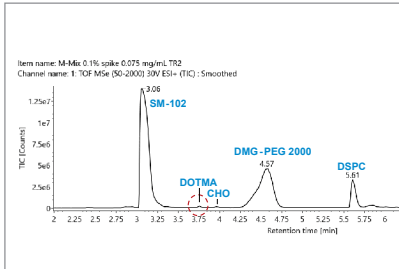
Streamlined attribute analysis and impurity analysis for therapeutic and vaccine development and commercialization.

- Intact Mass Confirmation
- MS2 Sequence Confirmation
- Impurity Identification and Quantification

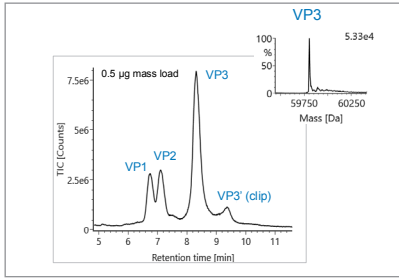




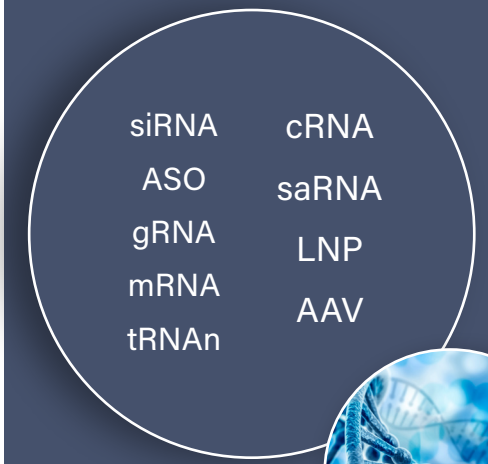
- Sequence Confirmation
- mRNA 5′ Capping Efficiency
- mRNA 3′ polyA Tail Heterogeneity



- LNP Component and Impurity Profiling
- Impurity Detection and Characterization



- Confirmation of Viral Particle Product Identity
- Profile and Map Subunit Modifications



"An ease of operation which has clearly never been seen before in other kinds of instrumentation"

Davy Guillarme, Research Associate, University of Geneva

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Complementary workflows for holistic analysis of nucleic acids and delivery vehicles

Unparalleled application-specific consumables, automation, and system-check standards for optimal performance and reproducibility

Purposely designed informatics with intuitive application workflows

waters_connect™

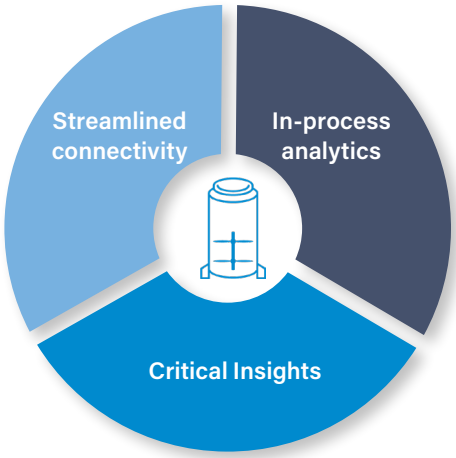
UNIFI™ | INTACT Mass | MAP Sequence | CONFIRM Sequence

The BioAccord System for Bioprocess Analytics

Simplify in-process analytics, monitor CQAs and CPPs and gain critical process insights to accelerate process development.

Out of the box connectivity for sample-to-result automation

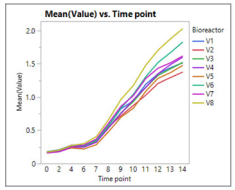
- Ambr® 250 High Throughput and Ambr® 15 system connectivity
- Bioprocess Walk-Up Solutions



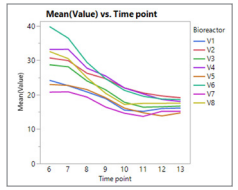
waters_connect™ → JMP®

Collate data, improve DOE and generate critical process insights

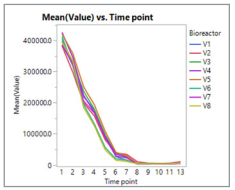
Titer



Quality



Media



Monitor in-process CQAs and CPPs on a single platform

- Identify CQAs
- Measure abundance
- Monitor trends with time course data

Titer

Glycans
(Intact, Reduced, Subunit)

Purity
(Aggregates/ fragments)

Peptide Monitoring

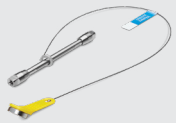
Cell Culture/
Spent Media

"The synergy between the BioAccord LC-MS System and the Ambr® bioreactor significantly enhances the efficiency of upstream process"

Dr. Li Wang, Director of BioDev Analytical Sciences, WuXi Biologics

Improve operational efficiency and analytical robustness with a readily-deployable platform solution

SARTORIUS



Unparalleled application-specific consumables, automation, and meaningful informatics connections

waters_connect™

Purposely designed informatics with intuitive application workflows

INTACT Mass

Bioprocess Monitor

Flexible: Configure your BioAccord System for your analytical needs

The BioAccord System is deployable from discovery to QC/Product Release and used for a wide variety of biopharmaceutical product and process analytical workflows. Configure your systems for the analyses you employ and the throughput you require.

Optical Detection

TUV/PDA
Add an FLR for Labeled Glycan Analysis

Sample Management

Variable or Fixed Loop Sample Injection

Configurable option to add Automation Portal Sample Interface

Configurable option to add Sample Organizer for Higher Throughput Analysis (up to 7680 samples)

Solvent Management

Binary UPLC (BSM) for Ultimate Gradient Fidelity

Quaternary UPLC (QSM) for Greater Mobile Phase Flexibility

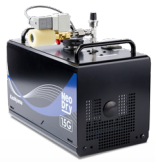
Column Management

Column Manager or Column Heater

Configurable option to add two Auxiliary Column Manager(s) for up to four additional columns

Configurable option to add 30 cm Column Heater/Cooler for LC columns up to 30 cm length and up to 7.8 mm diameter

Vacuum Pump System



Configurable option for Oil-based or Oil-Free (Air-Cooled) Vacuum Pump System for reduced Maintenance and Improved Environmental Sustainability

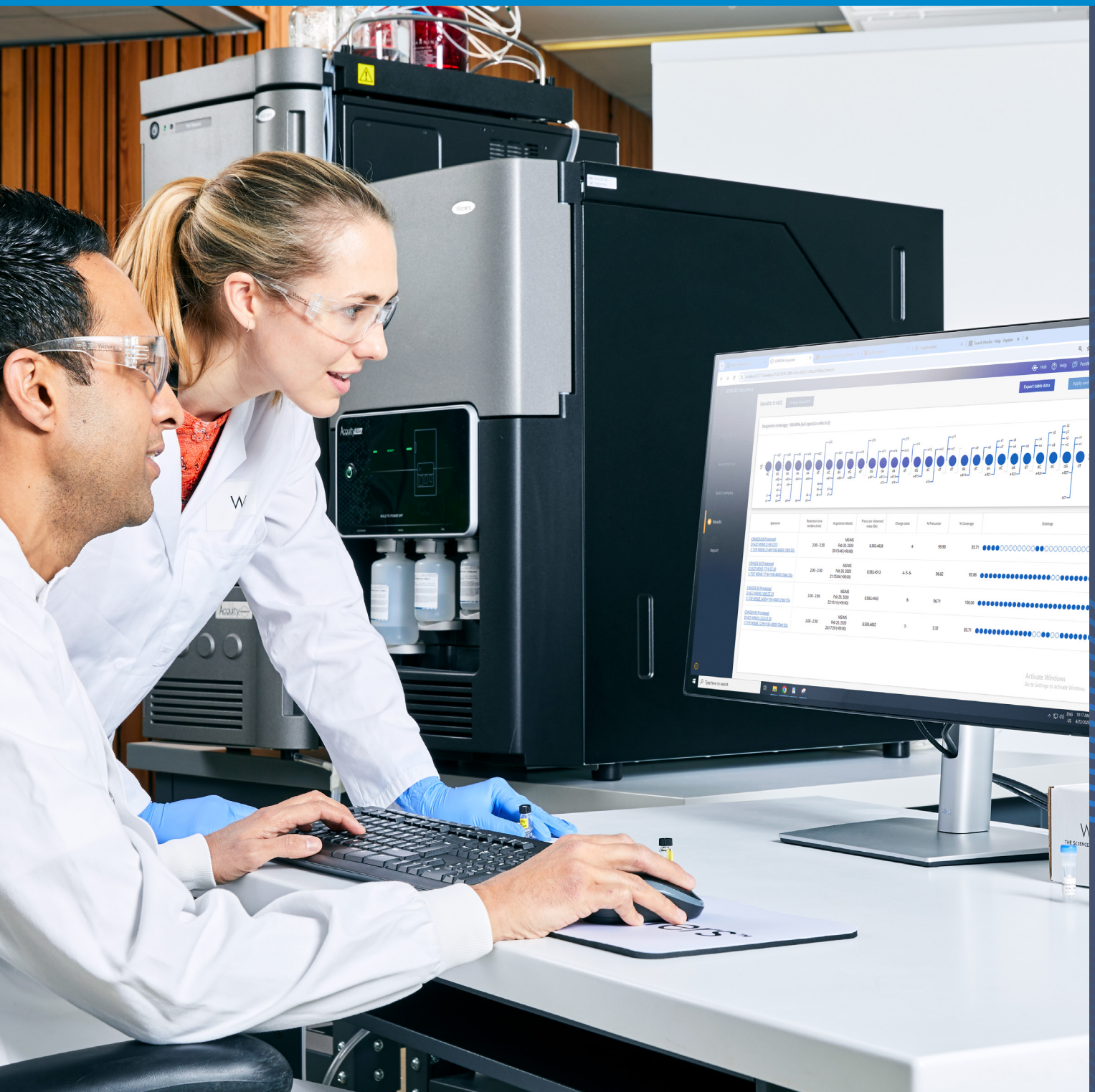
Made for Biopharma Analysis

- Developed and Tested with Biomolecules
- Installed and Trained with Biomolecules

Your trusted partner for success

- Outcome-Based Training with Dedicated Application Kits
- Highest customer satisfaction score for service and support among all instrument vendors.*

** According to SDi 2024 Analytical & Life Science Instrumentation Service Market (2021-2024 Users Perspectives)*



waters.com/bioaccord

Visit videos.waters.com to see the BioAccord LC-MS System in action

For your local sales office, please visit waters.com/contact

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Waters™