Raman bioprocessing solution compatibility with BioPAT® Spectro by Sartorius

Product overview

Integration highlights

- Raman model building in Ambr® systems
- Qualified, ready-to-use, single-use spectroscopy port for Biostat STR® bioreactors
- Raman model transfer from 15mL to 2000L lab-to-production scale

Endress+Hauser's Raman technology and BioPAT® Spectro integration overview

Collaboration between Endress+Hauser and Sartorius offers an exciting advancement in our already well-established Raman bioprocess product portfolio. The union between Endress+Hauser's Raman analyzers and unique bioprocess probes, and the BioPAT Spectro platform by Sartorius provides the market an ideal interface to high throughput development through single-use commercial manufacturing. Integrating Endress+Hauser Raman spectroscopy, powered by Kaiser Raman technology, into Ambr® enables Quality by Design (QbD) methods that are scalable to all sizes of Biostat STR® single-use bioreactors.

Endress+Hauser's Raman bioprocessing probe technology has been adapted to fit Sartorius's BioPAT Spectro platform, utilizing the same Kaiser Raman probe design for Ambr 15, Ambr 250, and Biostat STR bioreactors. This collaboration enables non-contact Raman collection, so no cleaning, sterilization, or frequent probe maintenance is required.

Key benefits of Endress+Hauser's Raman system integration with BioPAT Spectro from Sartorius:

- Raman integration with Ambr enables easier, faster, more price efficient, and more robust model building.
- Raman solutions are introduced to high-throughput process development which supports QbD.
- Raman provides a scalable approach and a more efficient transfer to Biostat STR for single-use manufacturing.

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Raman for Ambr®

The Raman Rxn2 embedded single channel analyzer is compatible with Ambr 15 and Ambr 250 for Raman model building and Raman monitoring of high-throughput cell culture process development. The two systems work together as follows:

- A Raman Rxn2 embedded analyzer with Raman RunTime software controls is fully integrated into the Ambr software.
- Ambr set-ups make full-time use of one Raman Rxn-46 probe to repeatedly collect spectra from each Ambr 15 or Ambr 250 vessel.
- Ambr software controls the Raman spectra data collection, and consolidates and stores all the data.
- Data from integrated at-line analyzers can be automatically aligned with the spectral data, or off-line data can be added manually during the run.
- After the run, a consolidated and contextualized data file can be exported from the Ambr software, ready for model building in SIMCA®.

Raman specifications for Ambr compatibility

Analyzer	Raman Rxn2 embedded analyzer
Location configuration:	Benchtop
Wavelength	785 nm
Probe	Rxn-46 bioprocess probe with BioPAT Spectro, Ambr, and Biostat STR by Sartorius
Probe configuration	Single channel
Software	Raman RunTime v6.2.2+ embedded software
User interface	Touch-screen starter kit
Fiber optic cable	5m electro-optical (EO) to EO fiber cable
Accessories	Raman probe calibration accessories, and Ambr flow cell light shield (sold by Endress+Hauser)

Raman for Biostat STR®

Raman Rxn2 and Rxn4 analyzers (single or four channel) with 785 nm wavelength are now compatible for single-use manufacturing. Embedded Raman Rxn systems include Raman RunTime version 6.2.2+ embedded software (a software update is available for non-embedded Raman Rxn systems). These systems work together as follows:

- Raman probes attach to the BioPAT Spectro single-use port.
- Ports come ready to use and fully qualified.
- Probe connection to the port is fast and simple.
- Raman collection requires no additional light blocking.
- Raman RunTime software initiates data collection from Biostat STR 50L – 2000L single-use bioreactors.

Raman specifications for Biostat STR® compatibility

Analyzer	Embedded or non-embedded Raman Rxn2 or Rxn4 analyzers
Location configuration:	Benchtop or cart-mounted (Raman Rxn2); rack-mounted or NEMA 4X enclosure (Raman Rxn4)
Wavelength	785 nm
Probe	Rxn-46 bioprocess probe compatible with BioPAT Spectro, Ambr, and Biostat STR by Sartorius, up to 4 per analyzer
Probe configuration	Single or four channel
Software	Raman RunTime v6.2.2+ embedded software (update needed for non-embedded RamanRxn systems); for Biostat STR connection to SCADA and the local controller is via OPC
User interface	Touch-screen starter kit
Fiber optic cable	EO to EO fiber cable (standard or custom length); or FC to EO fiber converter(s) for non-embedded systems
Accessories	Raman probe calibration accessories; SIMCA-Q v16+ predictor (available for purchase with Raman RunTime 6.2.2+ software); BioPAT Spectro STR mounting accessories (sold by Sartorius)

Endress+Hauser Raman lab-to-process solutions

With over 40 years of experience, Endress+Hauser is the global leader in Raman spectroscopic instrumentation for laboratory, process, and manufacturing environments. Our Raman analyzers, probes, software, and services are gold-standards used throughout the biopharmaceutical industry to optimize bioprocess efficiency and ensure product quality.

The Endress+Hauser Raman bioprocess product portfolio provides all the precise measurement required for the laboratory, along with cost effective scalability to the production environment. Our Raman analyzer systems measure many bioprocess parameters, enabling in-process, real-time bioprocess monitoring, control, and optimization.

By allowing for continuous measurement, our Raman solutions embrace process analytical technology (PAT) and enable biopharma companies to optimize, adapt, and control their processes. In doing so, Raman technology succeeds in achieving some high PAT objectives — minimizing process variability, waste, and development time, while maximizing data, productivity, process robustness, and product quality.

Benefits of our Raman bioprocessing solutions:

- Faster processing by reducing bottlenecks and analytical wait times
- Increased return on investment from process automation, reduced product waste, and higher yields
- Improved patient outcomes through process and quality improvements

Ultimate scalability: Our Raman probe materials and sampling areas are identical across all of our bioprocess probes - reusable, single use, micro-scale through large-scale. Our window material was selected specifically for bioprocess applications due to its high purity, low background, and lack of interfering peaks. This is different from traditional Raman window materials, such as sapphire, which drastically reduce the usable range of bioprocess spectra. Plus, our probes include self-alignment and calibration innovation for unparalleled method transfer capabilities.

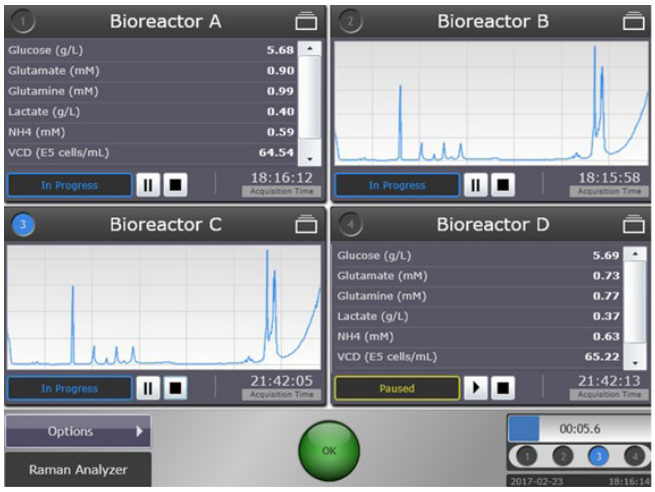
Raman embedded analyzers

Employing Industry 4.0 strategy

Endress+Hauser Raman embedded analyzers employ IIoT concepts by unifying hardware and software into a fixed purpose device with built-in intelligence. The analyzers communicate with external systems using standard automation protocols to collect and publish data and respond to commands. In doing so, our Raman technology embodies Industry 4.0 strategy of increased data security, system integration, and automated communication. All of our analyzers feature fully embedded Raman RunTime analyzer control software.

Key benefits of Raman embedded analyzers with Raman RunTime software:

- Reliability – no system modifications to disrupt correct operations, plus built-in, intelligent diagnostics
- Simplicity and consistency – streamlined physical installation, repeatable configuration, and familiar automation integration
- Extra space and security – secure remote access with possible headless installation to save valuable install space
- New features - safer, simpler and more robust EO fiber connectors as well as smart power controls, new electronics, and automation I/O



Rxn-46 probe calibration and verification kit

- Uses modular hardware to simplify Raman analyzer standardization and verification, contained in a convenient, all-in-one kit
- Facilitates easy calibration transfer of chemometric models for smooth lab-to-process scalability
- Offers flexibility to calibrate anytime without impacting your process, which simplifies redundancy and mitigates risk
- Enables quick instrument calibration and verification with minimal warm up, reducing down time
- Requires no external power for easier deployment in the field

The Endress+Hauser Raman difference

Not all Raman is created equal

Endress+Hauser offers world-class lab-to-process Raman spectroscopic instrumentation and analysis. In the biopharmaceutical and pharmaceutical industries, Endress+Hauser has many proven successes from development to manufacturing, traditional to single-use platforms, and batch-to-continuous bioprocesses. Our Raman bioprocessing technology stands far above other Raman alternatives because we offer:

- A proven ability to simplify process equipment complexity and ease method transferability from lab-to-manufacturing
- The most trusted, robust, scalable, and reliably performing Raman analyzers on the market
- Superior bioprocessing probes known for having the highest quality of contact materials and the most flexible sampling capabilities
- Experience, training, support, data modeling, and advanced analytics services to allow companies to focus on their core business while achieving a rapid ROI
- A 30+ year history of lab-to-process Raman leadership, expertise, innovation, and reliability
- 20+ years' experience in cGMP (10+ years leading the bioprocess PAT journey), with proven compliance, method transfer, and up time
- ISO 9001:2015 certification and experience hosting many successful audits by leading pharma/biopharma companies and suppliers
- Proven successes documented in hundreds of biopharma customer publications and thousands of other industry publications
- Award-winning products, including the Industry Aspen Award for Advancement of Upstream Bioprocessing (2017) and Pharma Manufacturing's 2020 Pharma Innovation Award
- The global support of Raman and process automation experts available worldwide, including an extensive local support network
- The security of knowing that we are part of the Endress+Hauser Group - People for Process Automation

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