

Kaiser Raman technology and Sartorius BioPAT Spectro[®] collaboration Q&A

Scalable, real-time bioprocess monitoring solutions

Benefits at a glance

- Enabling Raman integration with Ambr[®] for faster, more price efficient, easier, and more robust model building
- Introducing Raman spectroscopy solutions to high throughput process development, which supports companies' QbD efforts
- Providing a scalable approach and a more efficient transfer to Biostat STR[®] for single-use manufacturing
- Allowing method transferability across scales to other bioreactors
- Delivering non-contact Raman collection so no cleaning, sterilization, or frequent probe maintenance is required



Raman spectroscopy is used in biomanufacturing as a process analytical technology (PAT) tool, enabling rapid, non-destructive, in-process measurements. However, Raman data collection at early stages of bioprocess development has been a challenge since there was no interface to bioreactors less than 250 mL. Realizing the industry was struggling to capitalize on the full potential of Raman spectroscopy, Endress+Hauser collaborated with Sartorius to bring Raman to Ambr[®] 15 micro-bioreactors (10-15 mL) and

Ambr 250 mini-bioreactors (100-250 mL). Sartorius's new BioPAT Spectro[®] platform enables Raman-based Quality by Design (QbD) early on in process development and scales up to Biostat STR[®] single-use bioreactors.

This Q&A explains how Endress+Hauser Raman analyzer systems, powered by Kaiser Raman technology, and the BioPAT Spectro platform by Sartorius work together to provide biopharma manufacturers with scalable, real-time bioprocessing monitoring.



What makes this collaboration unique in the biopharmaceutical marketplace?

The adaption of Endress+Hauser's Raman Rxn-46 bioprocess probe represents the first instance of Raman being brought down to Sartorius's Ambr scale and Biostat STR single-use product lines. Integrating Raman spectroscopy into Ambr enables Quality by Design (QbD) methods that are scalable to all sizes of Biostat STR

single-use bioreactors. By providing fast, reliable and accurate measurement of key process variables from lab-to-process, the Raman Rxn-46 bioprocess probe (integrated with the BioPAT Spectro platform by Sartorius) empowers bioprocessing companies to more easily scale from development to cGMP while complying with strict quality standards.

What is the Raman Rxn-46 bioprocessing probe?

The Raman Rxn-46 probe is a specially designed version of our standard Rxn-45 bioprocessing probe, optimized to fit the BioPAT Spectro platform by Sartorius. It represents an exciting addition to the already well-established Endress+Hauser Raman bioprocess product portfolio, and a significant technological advancement for the biopharmaceutical industry at large. The union between Endress+Hauser Raman analyzers and bioprocess probe technology coupled with the BioPAT Spectro platform by Sartorius offers the market an ideal interface to high throughput development through single-use commercial manufacturing. Notably, the same Rxn-46 unique probe design is used for Ambr 15, Ambr 250, and Biostat STR bioreactors.

How do Endress+Hauser Raman analyzer systems work with Ambr?

For Raman model building and Raman monitoring of high throughput cell culture process development with Ambr 15 and Ambr 250, the Ambr platform works together with an Endress+Hauser Raman analyzer and the new Rxn-46 probe as follows:

- Endress+Hauser Raman analyzer controls are fully integrated into the Ambr software, which collects and stores Raman spectra matched to bioreactor data.
- After the run, a consolidated and contextualized data file can be exported from the Ambr software, ready for model building in SIMCA®. These predictive Raman models are then used for real-time monitoring and control of nutrients, metabolites, and cell properties.
- One automated Raman-enabled Ambr run can generate enough data to build highly robust models. In contrast, many manual runs are required for model data generation with traditional benchtop bioreactors. Additionally, traditional bioreactor runs lack design of experiment and analyte spiking, which are both built into the BioPAT Spectro solution.

How do Endress+Hauser Raman analyzer systems work with Biostat STR?

Endress+Hauser Raman analyzers are also compatible with Biostat STR with Flexsafe® bags from Sartorius for single-use manufacturing. These systems work together as follows:

- Endress+Hauser Rxn-46 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 is isolated from bubbles and ambient light.
- Endress+Hauser Raman software initiates spectral collection from Biostat STR 50L–2000L single-use bioreactors, and results can be communicated via standard automation protocols.



What makes the Raman Rxn-46 probe so compatible for use in bioprocessing?

The Rxn-46 probe features unique Endress+Hauser Raman bioprocess probe technology which is known for having the highest quality of contact materials and most flexible sampling capabilities in the industry. The probe window material was selected specifically for bioprocess applications due to its high purity, low background, and lack of interfering peaks, unlike traditional Raman materials which drastically reduce the usable range of bioprocess spectra. Probe materials and sampling areas are identical across all Endress+Hauser Raman bioprocess probes – reusable, single-use and micro-scale through large-scale. In addition, Endress+Hauser Raman probes include self-alignment and calibration innovation for unparalleled method transfer capabilities.

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