Kaiser Raman bioprocessing solution compatibility with BioPAT® Spectro by Sartorius

Product Overview

Integration Highlights

- Kaiser 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

Kaiser Raman and BioPAT® Spectro integration overview

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

Kaiser 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, & Biostat STR® bioreactors. This collaboration enables non-contact Raman collection, so no cleaning, sterilization, or frequent probe maintenance is required.

Key benefits of Kaiser Raman integration with BioPAT® Spectro from Sartorius:

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

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Kaiser Raman for Ambr®

The Kaiser 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:

- Kaiser 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 Kaiser Raman probe to repeatedly collect spectra from each Ambr® 15 or Ambr® 250 vessel.
- Ambr® software controls the Kaiser 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 offline 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®.

Kaiser Raman specifications for Ambr® compatibility	
Analyzer:	Kaiser Raman Rxn2 embedded analyzer
Location configuration:	Benchtop
Wavelength:	785nm
Probe:	Kaiser Raman bioprocess probe (bIO-PRO, KS) compatible with BioPAT® Spectro, Ambr®, and Biostat STR® by Sartorius
Probe configuration:	Single channel
Software:	Raman RunTime v6.3+ embedded software
User interface:	Touch-screen starter kit
Fiber optic cable:	5m EO to EO fiber cable
Accessories:	Kaiser Raman probe calibration accessories, and Ambr® flow cell light shield (sold by Kaiser)

Kaiser Raman for Biostat STR®

Kaiser Raman Rxn2 and Rxn4 analyzers (single or four channel) with 785nm wavelength are now compatible for single-use manufacturing. Embedded Raman Rxn systems include Raman RunTime version 6.2+ embedded software, (a software update is available for non-embedded Raman Rxn systems). These systems work together as follows:

- Kaiser 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.
- Kaiser Raman collection requires no additional light blocking.
- Raman RunTime software initiates data collection from Biostat STR® 50L – 2000L single-use bioreactors.

Kaiser Raman specifications for Biostat STR® compatibility

Analyzer:	Embedded or non-embedded Kaiser Raman Rxn2 or Rxn4 analyzers
Location configuration:	Benchtop or cart-mounted (Rxn2); rack-mounted or NEMA 4 enclosure (Rxn4)
Wavelength:	785nm
Probe:	Kaiser Raman bioprocess probe (bIO-PRO, KS) 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+ embedded software (update needed for non-embedded RamanRxn systems); for Biostat STR(R) 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:	Kaiser Raman probe calibration accessories; SIMCA-Q v16 predictor (available for purchase with Raman RunTime 6.2+ software); BioPAT(R) Spectro Support (locking mechanism from Sartorius)

Kaiser Raman lab-to-process solutions

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

The Kaiser Raman bioprocess product portfolio provides all the precise measurement required for the laboratory, along with cost effective scalability to the production environment. Kaiser Raman technology measures many bioprocess parameters, enabling in-process, real-time bioprocess monitoring, control, and optimization.

By allowing for continuous measurement, Kaiser Raman solutions embrace process analytical technology (PAT) and enable biopharma companies to optimize, adapt, and control their processes. In doing so, Kaiser 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 Kaiser 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: Kaiser 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 usability range of bioprocess spectra. Plus, our probes include self-alignment and calibration innovation for unparalleled method transfer capabilities.

Kaiser Raman embedded analyzers employing IIoT strategy

The newest Kaiser 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. Kaiser Raman's software technology, Raman RunTime, is embedded in the analyzers.

Key benefits of Kaiser Raman embedded analyzers with Raman RunTime software include:

- 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 Electro-optical (EO) fiber connectors as well as smart power controls, new electronics, and automation I/O
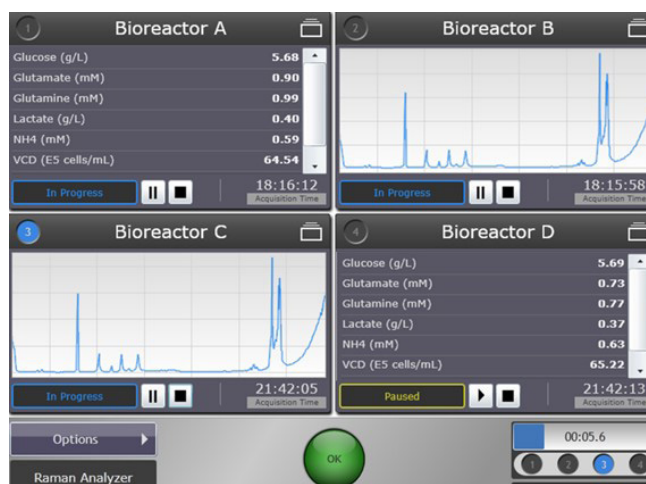
The Kaiser Raman Difference

Not all Raman is created equal

Kaiser Optical Systems, Inc. offers world-class lab-to-process Raman spectroscopic instrumentation and analysis. In the biopharmaceutical and pharmaceutical industries, Kaiser Raman has many proven successes from development to manufacturing, traditional to single-use platforms, and batch-to-continuous bioprocesses. Kaiser 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)
- The global support of Raman and process automation experts available worldwide, including an extensive local support network
- The security of knowing Kaiser is part of the Endress + Hauser Group - The People for Process Automation

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