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## Sartorius introduces BioPAT® Spectro to enable Raman spectroscopy capability and QbD with its ambr® and BIOSTAT STR® platforms

- Robust Raman model building in ambr® systems
- Raman model transfer from 15mL to 2000L single-use scale
- Qualified, ready-to-use, single-use spectroscopy port for BIOSTAT STR® bioreactors

Sartorius, a leading international partner of the biopharmaceutical industry today introduced BioPAT® Spectro, a Quality by Design (QbD) tool for use with its ambr® automated micro and mini bioreactor systems and with the single-use production bioreactors BIOSTAT STR®. The new tool offers access to Raman spectroscopy analysis in high throughput process development, supporting faster Raman model building and accelerating scale-up into commercial manufacturing.

Raman spectroscopy is non-invasive and can measure multiple analytes, making it suitable as a Process Analytical Technologies (PAT) method for process control and monitoring of cell cultures. Off-line approaches to obtain and consolidate enough data to produce a robust Raman model can be time-consuming and costly. The new BioPAT® Spectro Tool, can be retrofitted into ambr® 15 cell culture and ambr® 250 high throughput systems, and enables quick and simple sampling for integrated at-line analysis of a large number of analytes by Raman spectroscopy in a Design of Experiments (DoE) approach.

Consisting of a multi-use flow cell integrated into the ambr® analysis module, BioPAT® Spectro in ambr® has been successfully demonstrated by major pharmaceutical companies and is compatible with Raman spectrometers from Kaiser Optical Systems and Tornado Spectral Systems. The online Raman spectroscopy data alongside data from the ambr® process and selected integrated analyzers, is automatically collated by the ambr® software and can be easily transferred to SIMCA® Multivariate Data Analysis (MVDA) software to build robust Raman models.

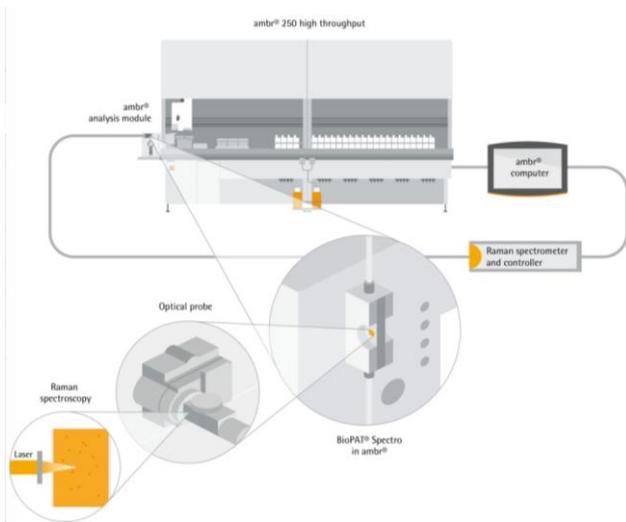
One benefit of using BioPAT® Spectro with ambr® system is that all integrated sampling, sample analysis, data collection, and consolidation is automated, making walk-away Raman spectroscopy analysis in high throughput process development a reality. Additionally, one ambr® run in 24 mini bioreactors can cover a wide design space, rapidly providing all the data required to build robust Raman models to support QbD, in less than half the time of the conventional benchtop approach.

Developed with scalability in mind, BioPAT® Spectro's flow cell's Raman probe interface and optical path design is identical across scales so it enables time-saving, automated in-line Raman spectroscopy with Sartorius' BIOSTAT STR® single-use bioreactors. The integrated qualified and ready-to-use single-use spectroscopy port in Flexsafe STR® bags for BIOSTAT STR® bioreactors will be launched in the near future.

"Unlocking the potential of Raman spectroscopy as a high throughput analytical technique for monitoring cell culture in mini bioreactors has been a key goal of process development scientists for a number of years," commented Dr. Svea Cheeseman, Product Manager Process Analytical Technology at Sartorius. "We are showcasing the BioPAT® Spectro at IFPAC and BPI West this year and look forward to discussing with scientists how they can use this new analytical

technique with ambr® systems to build and utilize robust Raman models, in a workflow which will support their QbD programs, while minimizing resource costs and biologics' manufacturing timelines," adds Dr. Cheeseman.

**Current image files:**



Caption: BioPAT® Spectro, a Quality by Design (QbD) tool for use with ambr® automated micro and mini bioreactor systems to enable Raman spectroscopy capability. Schematic showing the technology in use with ambr® 250 high throughput



Caption: ambr® 15 cell culture system with ambr® analysis module showing BioPAT® Spectro port; to which a probe for Raman spectrometer is connected

Link to download both images: <https://dam-system.sartorius.com/pinaccess/showpin.do?pinCode=iNNjImTIhFKF>

**A profile of Sartorius**

The Sartorius Group is a leading international partner of biopharmaceutical research and the industry. With innovative laboratory instruments and consumables, the Group's Lab Products & Services Division concentrates on serving the needs of laboratories performing research and quality control at pharma and biopharma companies and those of academic research institutes. The Bioprocess Solutions Division with its broad product portfolio focusing on single-use solutions helps customers to manufacture biotech medications and vaccines safely and efficiently. The Group has been annually growing by double digits on average and has been regularly expanding its portfolio by acquisitions of complementary technologies. In fiscal 2019, the company earned sales revenue of some 1.83 billion euros. At the end of 2019, more than 9,000 people were employed at the Group's approximately 60 manufacturing and sales sites, serving customers around the globe.

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