Ambr® Analysis Module

pH Calibration and Raman Spectroscopy Integration

Simplifying Progress

SARTORIUS

Ambr®
Analysis Module

Automates pH Calibration and Raman Spectroscopy for Ambr® Bioreactors

The Analysis Module provides add-on capability for automated measurement of pH, and optionally, Raman spectroscopy for Ambr® 15 and Ambr® 250 High Throughput bioreactors. The pH measurement automates initial bioreactor vessel pH sensor calibration and subsequent in-process re-calibration, and eliminates the operator time needed for manual offline pH measurement, data transfer and bioreactor pH sensor recalibration.

Ambr® Analysis Module Benefits

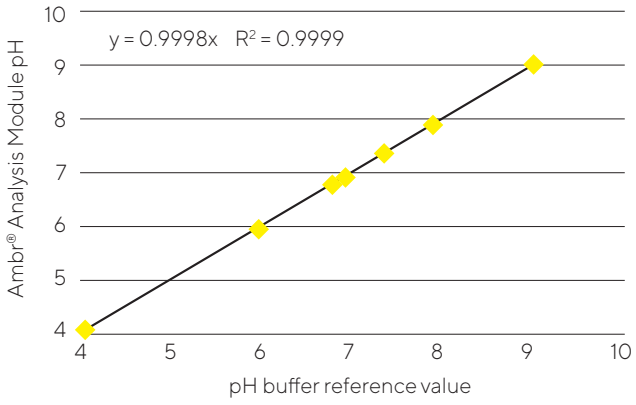
- Fully automated sample handling and assay
- Integration of 3rd party Raman spectroscopy probes and data flows
- Frequent, accurate pH sensor recalibration
- Reduced CO_2 outgassing effects and errors compared to manual offline pH samples
- User replaceable sensors (electrodes), Raman flow cells, and reagent kits
- Reagent kits including calibration solutions, cleaning solutions and a waste container

Ambr® Analysis Module is suitable for use with both cell culture and microbial media. It is not suitable for use with particulates (e.g. microcarriers will block internal tubing) or highly viscous cultures or samples (e.g. filamentous microbes).

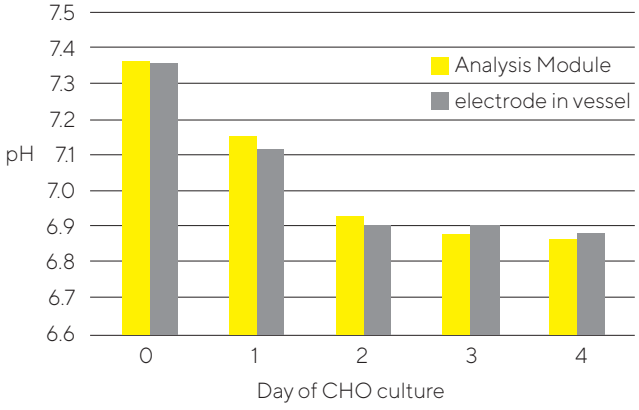
BioPAT® Spectro in Ambr® has been tested with CHO cell cultures but not microbial cultures. BioPAT® Spectro in Ambr® is suitable for use with mammalian fed-batch cell cultures but not high cell density perfusion cultures.

pH Calibration Performance

- Accurate, precise, linear response when reading a range of pH buffers



- Accurate, precise measurement of CHO culture pH
- Ambr® 15 CHO R&D test culture at Sartorius Royston
- N = 24 bioreactors, ~ 10^6 cell/mL at day 6
- Reference measurement: Mettler electrode inserted into Ambr® 15 vessel



Find out more
https://www.sartorius.com/en/products/process-control-data-analytics/process-analyzers/biopat-spectro

Specifications

Parameter	Ambr® 15	Ambr® 250 High Throughput
Sample volume, pH	60 µL	250 µL
Sample volume, BioPAT® Spectro	160 µL	200 µL
Cycle time per reading, pH	90 s	120s
Cycle time per reading, BioPAT® Spectro	10-15 min	10-15 min
pH Resolution	0.01	0.01
pH buffer accuracy	±0.01	±0.01
BioPAT® Spectro in Ambr® requirements	Compatible Kaiser/Tornado Raman spectrometer and BioPAT® Spectro probe. SIMCA 16 license (not included). Win10 Ambr® control PC.	

BioPAT® Spectro in Ambr®

Enables Integration of Raman Spectroscopy

BioPAT® Spectro in Ambr® enables the automated integration of Raman spectrometers from Kaiser Optical Systems and Tornado Spectral systems, via a Sartorius-specific fiber optical probe.

BioPAT® Spectro in Ambr® Benefits

- Automated consolidation and contextualization of all spectral and process data into a SIMCA®-ready file for model building
- Ambr® derived Raman models are more robust due to the use of all process data, a large DoE design space, and automated spiking of Ambr® samples with analyte stock solutions
- Ambr® can use SIMCA® models to predict analyte concentrations and execute process control in real time

▲ BioPAT® Spectro flow cell with Kaiser Optical Systems probe connected. Prototype pictured.

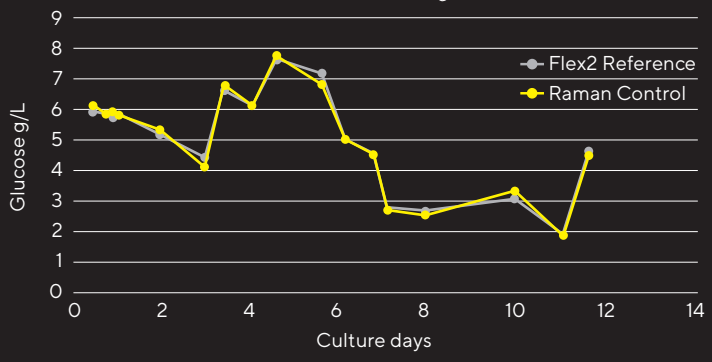
▶ BioPAT® Spectro flow cell with Tornado Spectral Systems probe connected

Find out more
https://www.sartorius.com/en/products/process-control-data-analytics/process-analyzers/biopat-spectro

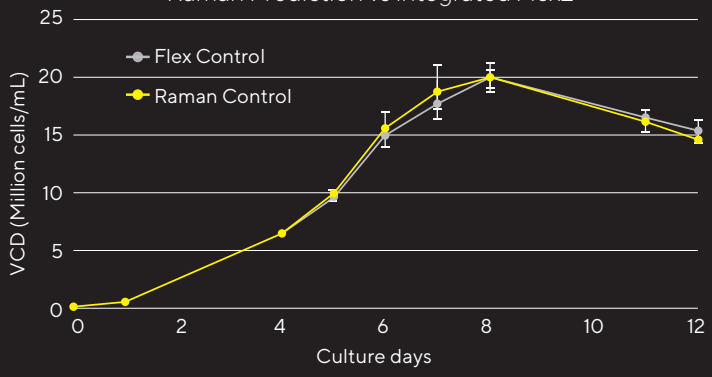
BioPAT® Spectro in Ambr® Performance

- A model building Ambr® 250 High Throughput run (N=8) was carried out using a Cellca2 CHO mAb process
- >200 data points were automatically assayed by integrated Nova Bioprofile® FLEX2 and an integrated Raman analyzer
- Raman, FLEX2 and Ambr® process data were automatically collated in the Ambr® software
- A separate copy of SIMCA® software was used to build a Raman glucose model
- A second Ambr® 250 High Throughput Cellca2 run (N=12) was carried out to assess process performance based on real-time Raman predictions (N=6) in comparison to integrated Nova FLEX2 (N=6)
- (A) Raman glucose predictions matched very closely to FLEX2 measurements (N=1 shown for clarity)
- (B) Cell culture profiles were very consistent and equivalent for glucose control based on either integrated Raman (N=6) or FLEX2 (N=6) analyzers

A. Glucose measurement using
Raman Prediciton vs integrated Flex2

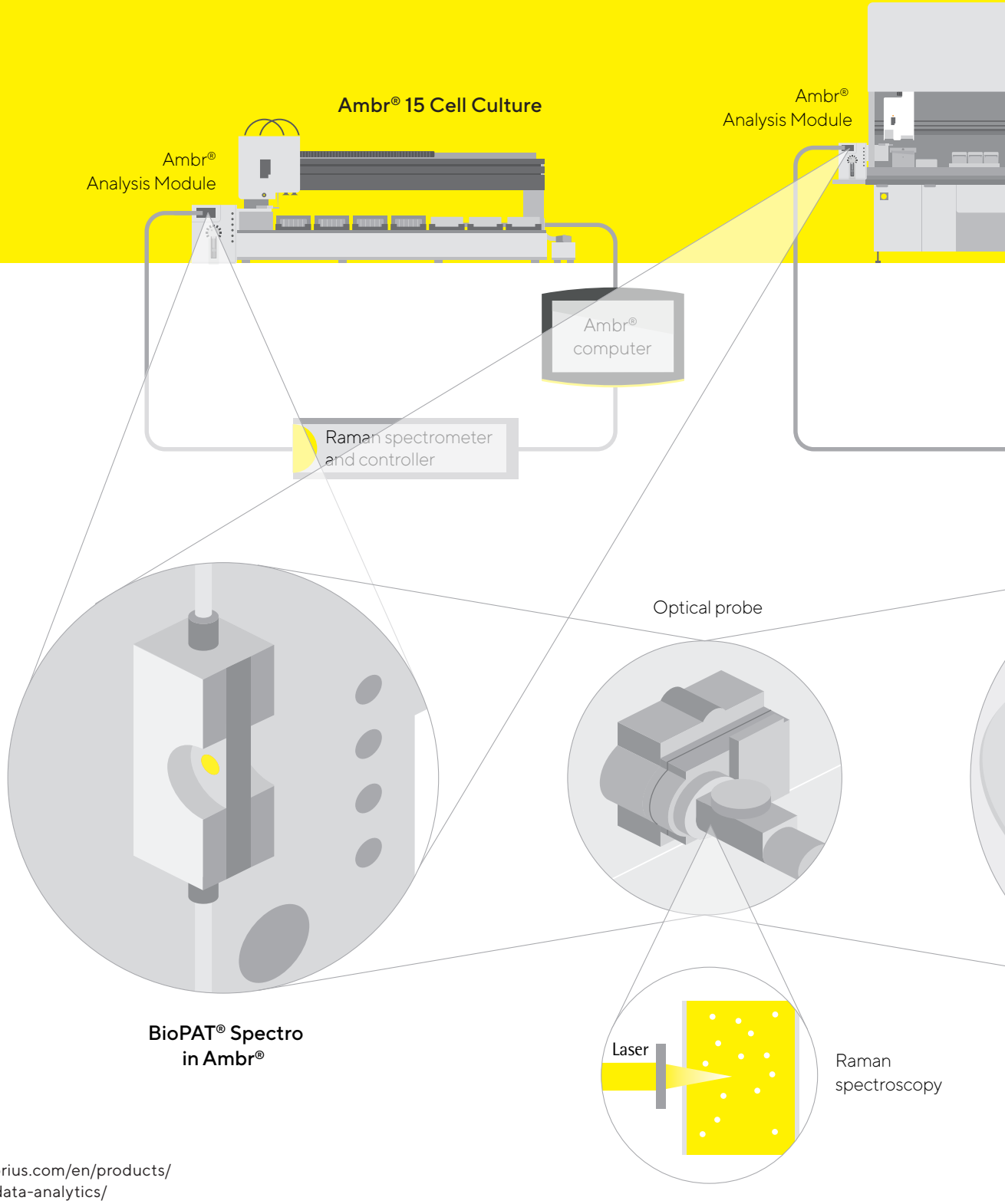


B. Glucose control using
Raman Prediction vs integrated Flex2



BioPAT® Spectro Platform

Meeting the Needs of Process Development and Commercial Manufacturing



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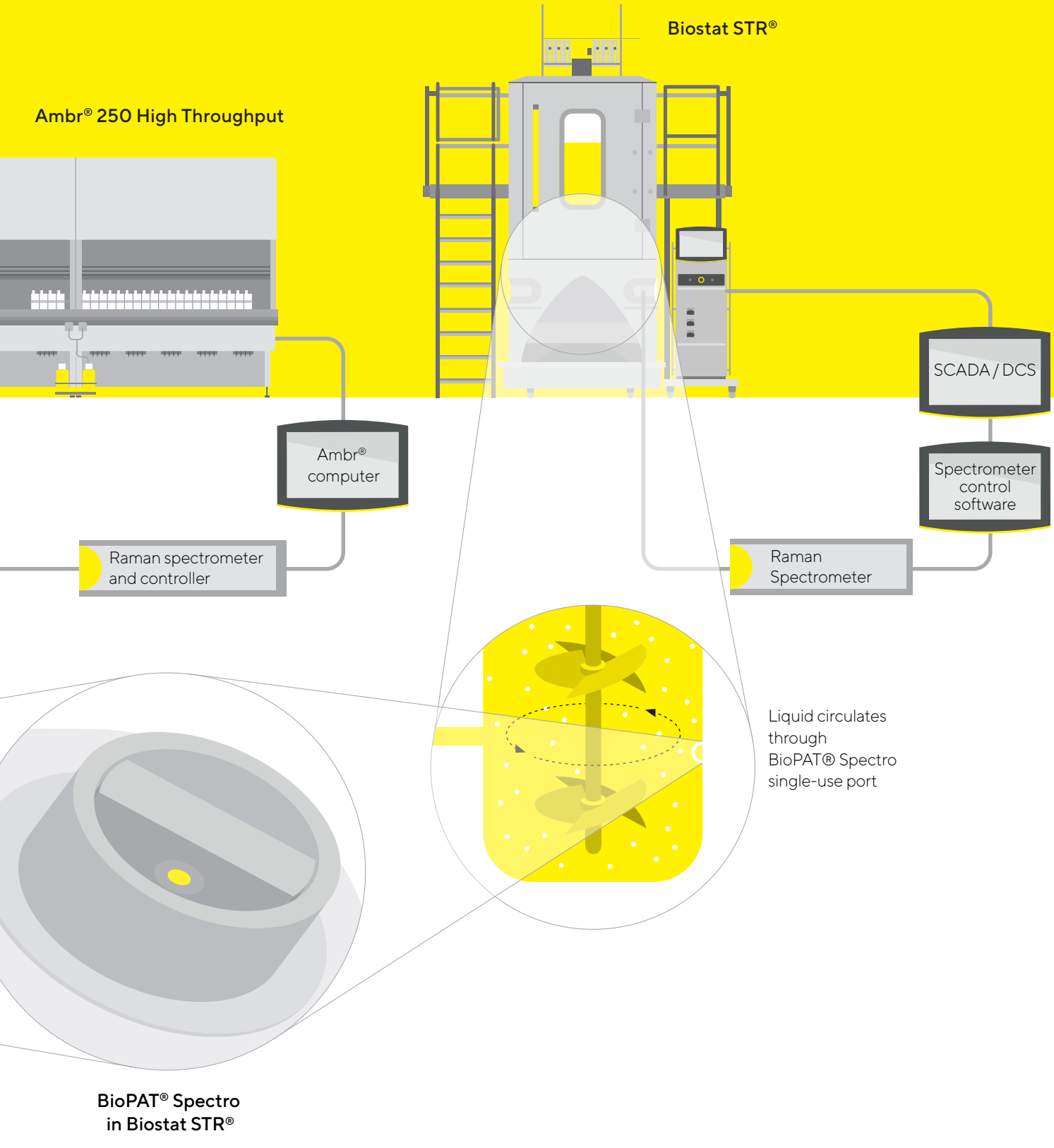
Biostat STR®
Ambr® 250 High Throughput
SCADA / DCS
Ambr® computer
Spectrometer control software
Raman spectrometer and controller
Raman Spectrometer
Liquid circulates through BioPAT® Spectro single-use port
BioPAT® Spectro in Biostat STR®

Consumables

Operation of the Analysis Module is supported by replaceable sensors (electrodes), a replaceable BioPAT® Spectro flow cell, and reagent kits including calibration solutions, cleaning solutions and a waste container. Replacement of electrodes and reagent kit is recommended every 3 months for optimum measurement accuracy.

BioPAT® Spectro flow cell for Ambr® Analysis Module
Part no. 001-8B78

pH and reference electrodes
Part no. 001-4B80

Reagent kit, pH
Part no. 001-4B60

Sales and Service Contacts

For further contacts, visit www.sartorius.com

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