



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 Ambr[®] Analysis Module provides add-on capability for automated measurement of pH and 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 recalibration, and eliminates the operator time needed for manual offline pH measurement, data transfer and bioreactor pH sensor recalibration.

Ambr[®] Analysis Module Benefits

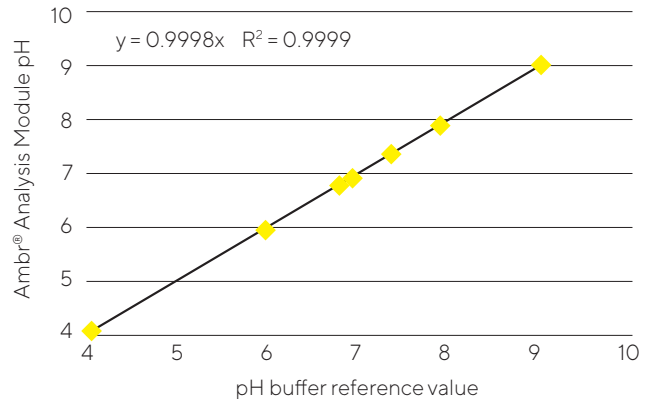
- Full automation of pH measurement sampling and assay
- Reduced CO₂ outgassing effects and errors compared to manual off-line pH sampling
- Automated accurate pH sensor recalibration
- Optimised pH measurement modes for normal and high cell density cultures
- Allows integration of 3rd party Raman spectroscopy probes and data flows
- User replaceable pH sensors, Raman flow cells, and reagent kits

The Ambr[®] Analysis Module is suitable for use with both cell culture and microbial media and supports two user-selectable measurement modes for cell cultures up to at least 100 million cells/mL. It is not suitable for cultures containing particulates (beads or microcarriers, for example) or highly viscous samples.

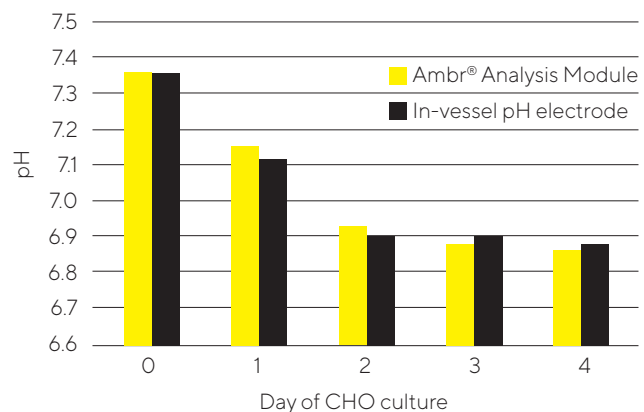
BioPAT[®] Spectro in Ambr[®] has been tested with CHO cell cultures but not microbial cultures. BioPAT[®] Spectro in Ambr[®] is suitable for use with mammalian fed-batch cell cultures but has not been evaluated with high cell density perfusion cultures.

pH Calibration Performance

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



- Accurate, precise measurement of CHO culture pH
- Ambr[®] 15 CHO culture
- N = 24 bioreactors, ~10⁶ cell/mL at day 6
- Reference measurement: Calibrated electrode inserted into Ambr[®] 15 vessel



Find out more

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	200 µl
Sample volume, BioPAT® Spectro	110 – 200 µl	110 – 200 µl
Cycle time per reading, pH	160 s	160 s
Cycle time per reading, BioPAT® Spectro	5 – 15 min	5 – 15 min
pH Resolution	0.01	0.01
BioPAT® Spectro in Ambr® requirements	Compatible Kaiser/Tornado Raman spectrometer and BioPAT® Spectro probe. Appropriate SIMCA® 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

BioPAT[®] Spectro in Ambr[®] Performance

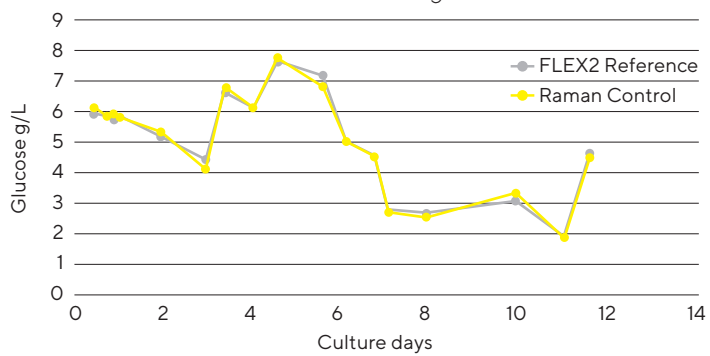
- A model building Ambr[®] 250 High Throughput run (N=8) was carried out using a Cellca2 CHO mAb process
- >200 data points were automatically assayed by integrated BioProfile FLEX2 and an integrated Raman analyzer
- Raman, FLEX2 and Ambr[®] process data were automatically collated in the Ambr[®] software
- 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 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

Find out more

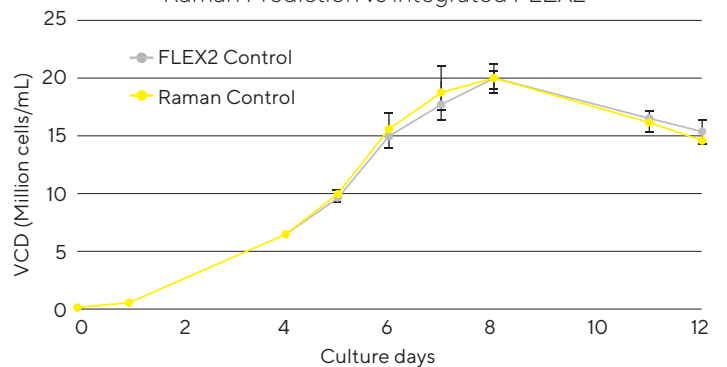
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A. Glucose measurement using Raman Prediction vs integrated FLEX2

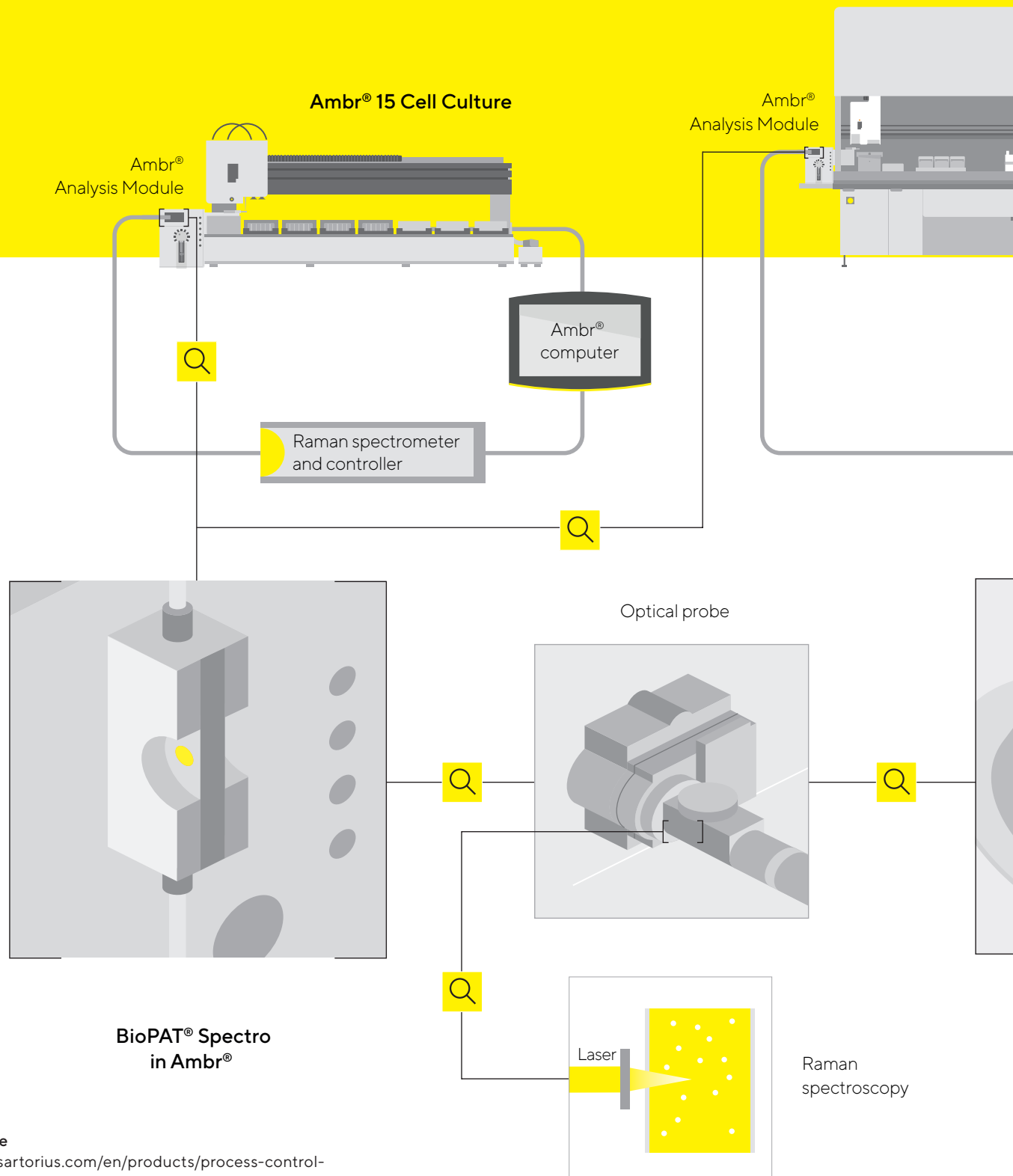


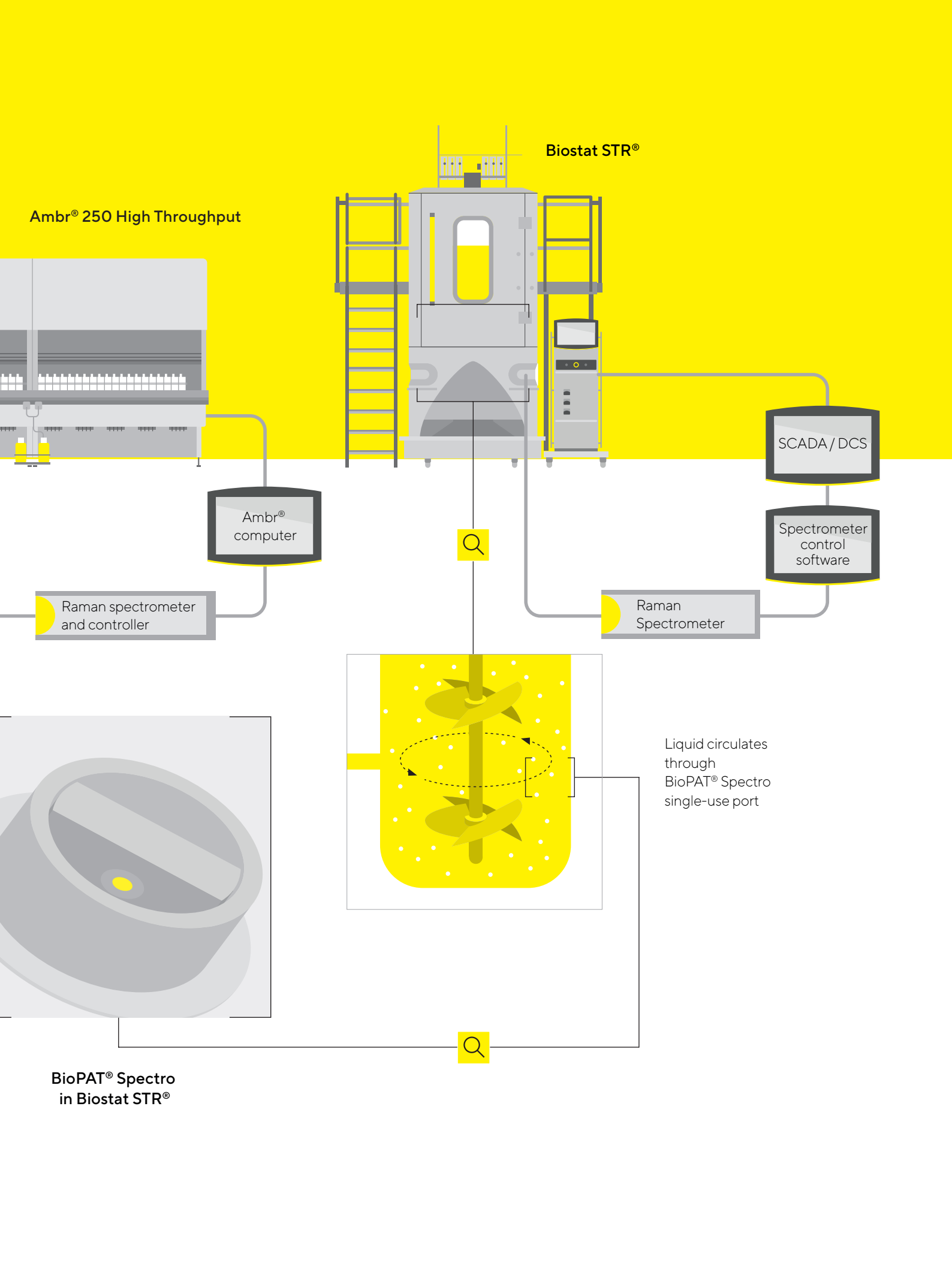
B. Glucose control using Raman Prediction vs integrated FLEX2



BioPAT[®] Spectro Platform

Meeting the Needs of Process Development and Commercial Manufacturing





Consumables

Operation of the Ambr® Analysis Module is supported by replaceable sensors, a replaceable BioPAT® Spectro flow cell, and reagent kits including calibration solutions, cleaning solutions and a waste container. The ability to reliably measure pH is process, cell line, and cell density dependent. It is recommended pH and Reference sensors be replaced at least every 3 months. Actual lifetime will be dependent on process application and may necessitate more frequent replacement.



BioPAT® Spectro flow cell for Ambr® Analysis Module



pH and reference electrodes



Reagent kit, pH

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