Biacore™ Insight Software

LABEL-FREE INTERACTION ANALYSIS

Biacore™ Insight Software is the platform for efficient instrument control and data evaluation of Biacore 1 series and Biacore 8 series systems (Fig 1). It provides a streamlined approach to run, analyze, visualize, and export your surface plasmon resonance (SPR) data. Pick the right tool for your application needs with a variety of optional software extensions for additional functionality and tools to optimize your analysis and reduce time to result. The intuitive and modular software design allows you to maximize application versatility and expand system usage to your current needs, regardless of experience, use case, or stage of research.

Our software consists of:

- **Biacore Insight Control Software.** With predefined run methods covering a wide range of applications, the software provides guidance and support for assay set up, with changeable settings for sample run order, control intervals and sample concentrations.
- **Biacore Insight Evaluation Software.** Analyze your data with just a few clicks. It is equally suited for the rapid analysis of large screening campaigns and deep kinetic characterization of a single interaction, epitope binning experiments, or reproducible quantitation of your samples.
- **Biacore Insight Database.** Allows you to have full control of all your data while improving data safety and integrity compared to file-based systems.
- **Biacore Insight API Server.** Enables the automated integration of Biacore SPR system data into your lab information management systems via an application programming interface (API).
- **Cytiva Software Licensing Manager.** Enables the use of floating licenses that allow you to share access rights between users and computers, and removes restrictions on the number of simultaneously installed copies of the software.

SPR made simpler and faster

Biacore Insight Software provides support to you, irrespective of experience to further streamline your analysis and reduce time to result.

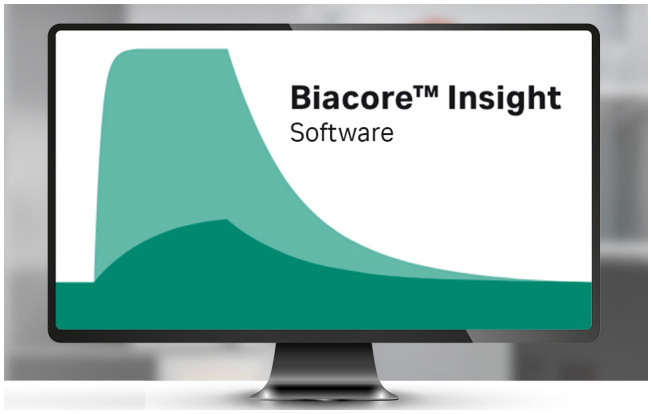


Fig 1. Biacore Insight Software provides a streamlined approach to run, analyze, visualize and export your SPR data.

- **Streamlined, easy to use approach to run, analyze and visualize SPR data** with predefined methods and quality control tools to shorten time to conclusive results.
- **Flexible analysis platform that grows with your project needs** via optional, application specific software extensions that maximize platform versatility, and improve visualization of your data.
- **Evaluate your data like the experts in minutes not hours** with Biacore Intelligent Analysis™ software: machine-learning models pretrained by Cytiva's Biacore scientists for efficient and robust analysis of large data sets.
- **Simplified analysis of all your Biacore SPR data with a unified evaluation software** for Biacore T200, Biacore S200, Biacore 8 series and Biacore 1 series SPR systems.
- **Easy export of data and compilation of results:** Quickly make publication-ready figures, create reports and presentations customized to your needs. Export large data sets for aggregation and further analysis.
- **21 CFR Part 11 compliance** enables integration into GxP-regulated workflows including electronic signatures, audit trials and published procedures.

Biacore Insight Control Software

Biacore Insight Control Software is the unified instrument control software for Biacore 1 series and Biacore 8 series systems. It enables efficient method definition and operation. The adaptable, predefined methods are preloaded with application-relevant default settings and are available for all major assays. With its intuitive easy-to-use interface, you are able to design experiments quickly. The ***Activity queue*** (Fig 2) allows to you to queue up methods, which minimizes unnecessary wait times and maximizes throughput. Immobilization methods, analysis methods, cleaning procedures, temperature changes, and other relevant steps, can all be added to the queue in a fully flexible manner.

With the capability of controlling Biacore 1 series and Biacore 8 series instruments, the software also has additional features to easily transfer methods between instruments.

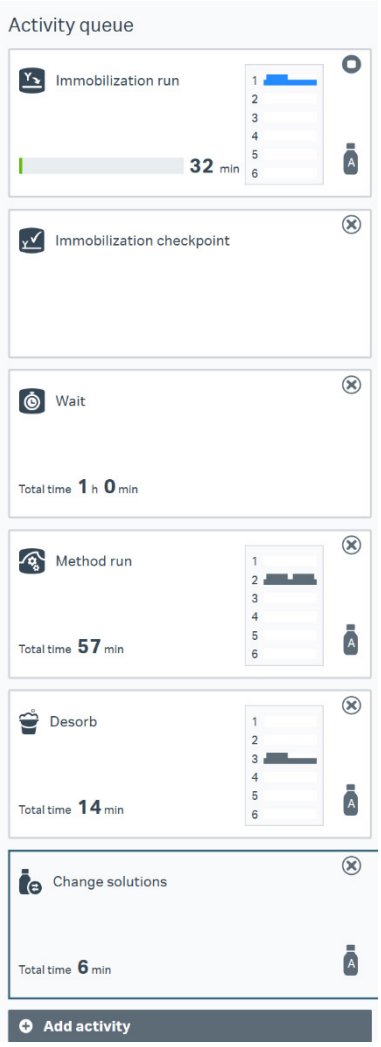


Fig 2. The ***Activity queue*** showing immobilization and run methods as well as maintenance routines queued up for processing by a Biacore system.

Biacore Insight Evaluation Software

Biacore Insight Evaluation Software is an easy-to-use and efficient tool for the evaluation of all your Biacore SPR data. Predefined, application-specific evaluation methods developed by our Biacore scientists and engineers allow you to standardize, simplify data analysis and avoiding repetitive tasks. Use them as a template for your optimized user-defined evaluation methods or use them as is.

When opening a run file with the selected evaluation method, the first results are obtained in seconds, shortening time to decision. From the analysis of large screening campaigns to deep kinetic characterization of single interactions, the flexible tools scale with the size of your experiment — providing results you can trust. The evaluation interface (Fig 3) is configurable to maximize the space for your most important tasks at any time:

- Get a rapid overview and quickly qualify your data.
- Utilize flexible tools to customize your data analysis.
- Easily export and share your results using Microsoft PowerPoint format.
- Simultaneously visualize your results from thousands of samples.

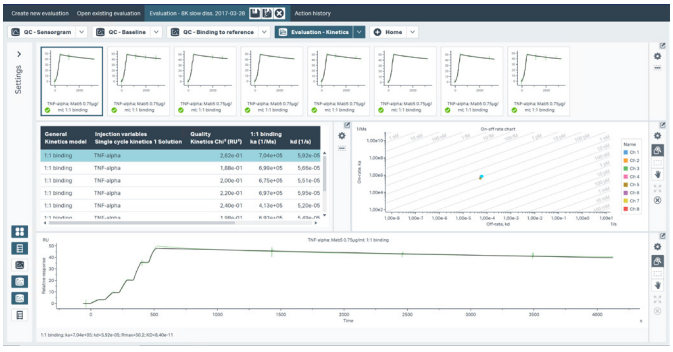


Fig 3. The flat interface of Biacore Insight Evaluation Software provides full overview while offering flexible tools for customized data analysis. The overview allows convenient simultaneous visualization of kinetics and affinity data providing ***Result table***, ***On-off rate chart***, and **K_D chart**.

Automated quality control tools analyze SPR-data-fitting quality for the magnitude of kinetic constants, parameter uniqueness, bulk refractive index, and residuals. This enables you to interpret results with ease and confidence via a simple traffic light visualization.

Expand the capabilities of binding level and affinity screens

The optional Biacore Insight Extended Screening Extension contains a variety of features, that help shorten time to result for the entire SPR workflow in drug discovery screening for Biacore T200, Biacore S200, Biacore 8 series and Biacore 1 series SPR systems.

Predefined methods for running and evaluation of screening experiments give you a head start.

- ***Clean screen*** enables you to efficiently cleanup both low molecular weight (LMW) and fragment libraries and easily identify sticky, residual binders to the sensor chip surface, minimizing the risk of false negatives.
- ***Binding level screen*** allows you to rapidly identify, rank and prioritize primary hits for follow-up analysis based on their binding response and binding behavior to the target, while excluding fragments with atypical binding or non-desirable behavior.
- ***Affinity screen*** enables you to verify target binding and obtain steady-state affinities of fragments to the target. Affinities for fragments are often in the millimolar to high micromolar range. Fitting with a constant control determined R_{max} facilitates determination of such low affinities.

In addition, adaptable binding behavior markers automatically annotate your screening results delivering key insights in the sensorgram data, making it faster and easier to filter out false positives (Fig 4).

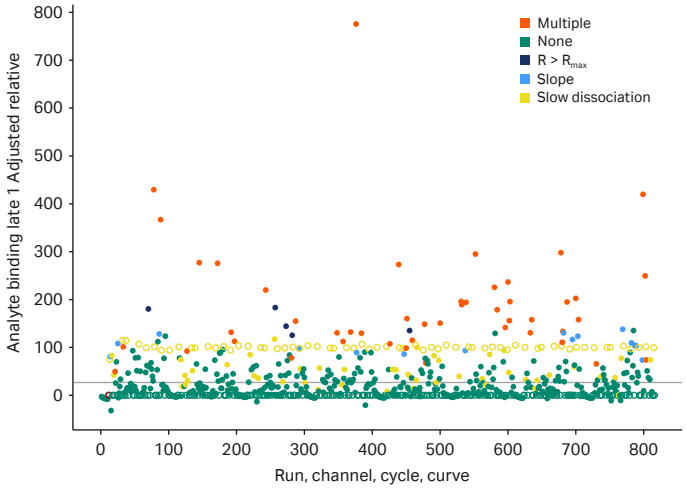


Fig 4. Plot of fragment screen results analyzed with binding behavior markers. The automatic evaluation marks the samples. The settings for how sensitive the automatic evaluation applies these markers can be adjusted by the user.

Guidelines throughout the visualizations enhance your understanding of the data and provide you with additional information right where you need it (Fig 5). Guideline curves in the ***Plot*** item enhance first look evaluation capabilities by adding reference surface sensorgrams and ideal fragment shape profiles. Guidelines in the ***Affinity*** item show you an expected R_{max} line and alternative constant R_{max} fit line for easier interpretation and selection of affinity data.

The ***Fast injection*** command in Biacore Insight Control Software improves the throughput for applications like ***Clean screens*** and first pass screens.

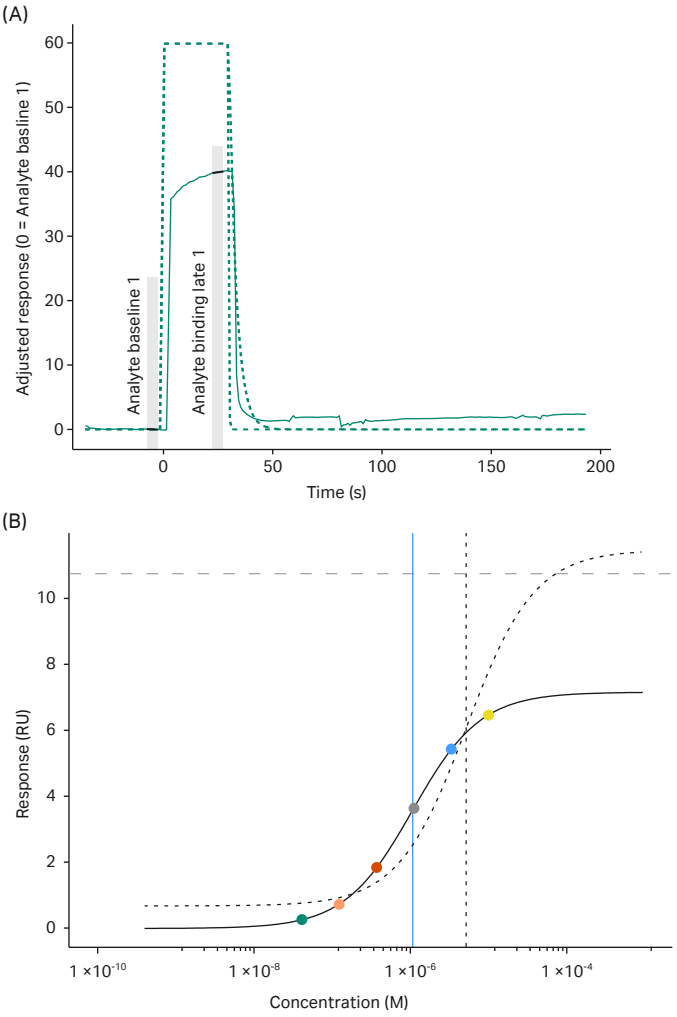


Fig 5. (A) selecting any point in a plot item will display the corresponding sensorgram data. Additional guidelines can be activated to show ideal fragment shape and the reference surface sensorgram. (B) Affinity plot showing the constant R_{max} fit line together with the free fit. Vertical lines for K_D values and a horizontal line for the expected R_{max} help in your evaluation process.

Significantly reduce the analysis bottleneck in binding level and affinity screens with Biacore Intelligent Analysis software

Biacore Intelligent Analysis software enables the consistent and automated analysis of large data sets by significantly reducing the manual, time-consuming steps of data curation and quality control. This optional, add-on extension offers support for two analysis types, ***Binding level screen*** and ***Affinity screen*** from Biacore T200, Biacore S200, Biacore 8 series and Biacore 1 series SPR systems.

Biacore Intelligent Analysis software comes with prediction models, pretrained by our scientists. The prediction models provide a ready-to-go solution for analysis for fragment binding level and affinity screening data. They are validated to provide greater than 90% accuracy as opposed to human expert analysis with excellent sensitivity (> 87%) and specificity (> 90%).

Biacore Intelligent Analysis software for ***Binding level screen*** applications, automatically analyzes and classifies your binding level data via a series of feature:

- ***Binder prediction quality*** automatically predicts the quality of the interaction (high, low, or uncertain).
- ***Binder prediction classifications*** are automatically applied to allow the user to understand the reasons for the assigned prediction quality and trace that prediction back to the underlying sensorgram data. These classifications can be customized when starting with an untrained model.
- ***Binder prediction certainty*** is a percentage measure of how confident the model is in the prediction of binder prediction quality (Fig 6).

Fig 6. ***Binding level screen*** analyzed by Biacore Intelligent Analysis software.

Biacore Intelligent Analysis software for ***Affinity screen*** helps you analyze concentration series experiment with steady-state affinity. Automations include:

- Selection of the ***Affinity range*** position to deal with added non-specific binding and series reaching steady state only close to the end of injection.
- Exclusion of outliers in the concentration series removes the need for manually curation of the concentration series.
- Selection of the appropriate R_{max} fit settings (constant versus fitted) enables better characterization also for low affinity interactions.
- Customizable classifications are applied to the series further characterizing the interaction and setting the basis for final data quality assessment.
- Results for both fits are displayed and assigned into three categories: ***Accept***, ***Reject***, or ***Uncertain***.
- An acceptance certainty is calculated and shows how confident the model is in the prediction (Fig 7).

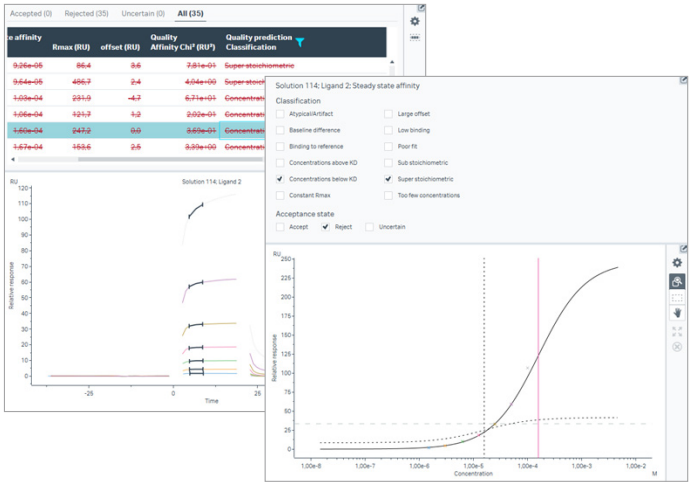


Fig 7. Fragment ***Affinity screen*** analyzed by Biacore Intelligent Analysis software.

You can override any predictions that the prediction models have made, and assign your own analysis to the data at any time. To make changes to the prediction model, simply select ***Train new version***. The prediction models you create (either from the blank or naive models or by retraining the pre-trained prediction models provided) can be managed, tracked, and annotated in the prediction model manager. When a prediction model is established, you only need to assess the few ***Uncertain*** samples, reducing the evaluation effort by up to 80%. You also have the option to import or export prediction models to share between groups and collaborators and drive standardization in your analysis, projects, and programs.

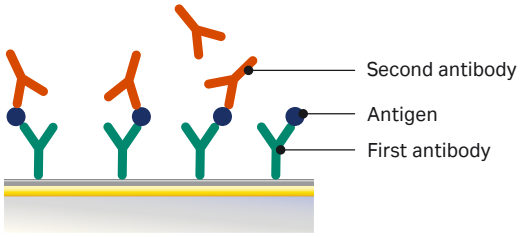
- Reduces the time to analyze large data sets by more than 80%.
- Reduces user error and improves consistency in data analysis, driving standardization across projects and teams.
- Data annotation allows users to rapidly check and understand machine-learning-based decisions.

- Pre-trained prediction models by our Biacore scientists provide out-of-the-box functionality.
- Option to further train prediction model over time using your own data or start with an untrained, naive model.
- Prediction model manager allows user to import, export, track, and manage prediction model versions.

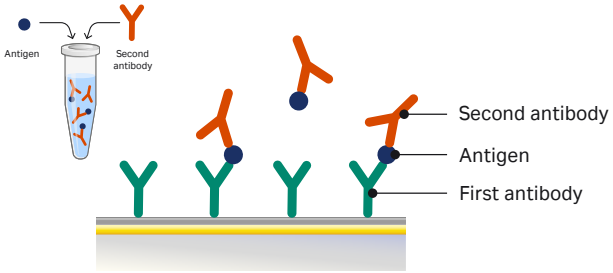
Rapid overview of epitope diversity to identify and maintain unique protein binding sites

Biacore Insight Epitope Binning Extension enables automated identification and control to maintain unique and diverse epitopes that may broaden intellectual property protection. This add-on, application-specific extension provides support from run setup through to data evaluation, including predefined methods and an automatic sample plate layout tool to shorten your assay development. All three main assay formats for epitope binning analysis are supported: sandwich, tandem, and premix (Fig 8) from Biacore T200, Biacore S200, Biacore 8 series and Biacore 1 series SPR systems.

Sandwich assay



Premix assay



Tandem assay

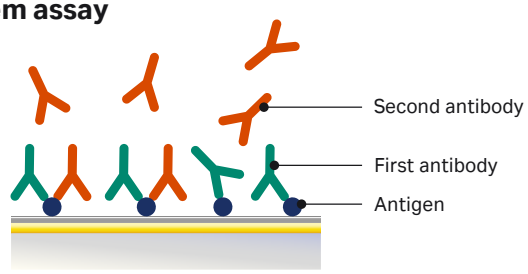


Fig 8. Three different assay formats to run epitope binning experiments, all supported by Biacore Insight Software.

A challenge in epitope binning is that the low affinity of binding between the antigen and the first antibody can lead to dissociation of the antigen, resulting in the underestimation of binding level of the second antibody. ***Dual*** command compensates for this by injecting the antigen and the second antibody solutions in sequence without delay between injections, minimizing the dissociation of antigen before the secondary antibody is injected (Fig 9).

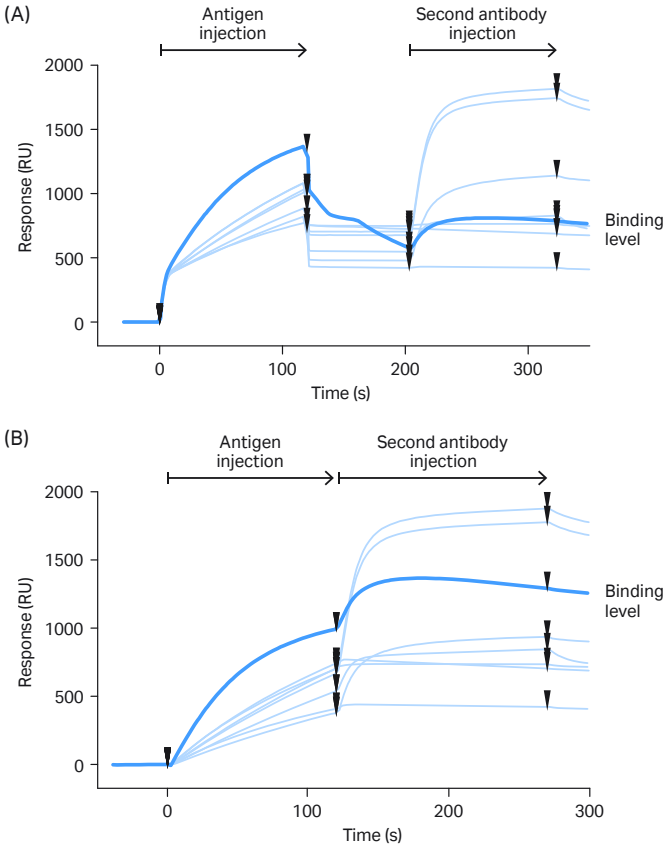


Fig 9. ***Dual*** command minimizes the dissociation of antigen before second antibody is injected, facilitating data interpretation. (A) Weak interaction between first antibody and antigen may lead to underestimation of second antibody level. (B) ***Dual*** command enables interpretation of fast dissociating antigens for binning experiments.

A predefined evaluation method automatically processes data generated on Biacore 1 series, Biacore 8 series, Biacore T200 or Biacore S200 systems with the relevant evaluation settings.

Sensorgram overlay shows cut-off and read-out intervals. The sensorgrams are automatically aligned and injections are assigned according to the method. The heatmap provides a rapid overview of blocking, non-blocking and uncertain antibody pairs, and allows for straightforward inspection of data in the heat map, as well as easy adjustments of cut-offs in the corresponding sensorgrams.

Additionally, the new bin chart provides an intuitive and easy approach to illustrate and visualize epitope diversity. Different bins containing corresponding antibodies are displayed in different colors, clusters of overlapping bins are separated by gaps, and can additionally show bin connections (i.e., unidirectional blocking behavior), curve markers and antibody tags. The streamlined evaluation support in Biacore Insight Epitope Binning Extension makes data evaluation efficient through the automatic analysis and visualization of bins (Fig 10). All visualizations are dynamically updated when thresholds or settings are changed.

- Visualize your protein epitope diversity quickly — from assay setup to data interpretation.
- Built-in support for main binning formats — sandwich, tandem, and pre-mix assay formats.
- Overcome unstable binding of antigen to primary antibody with ***Dual*** injection command.

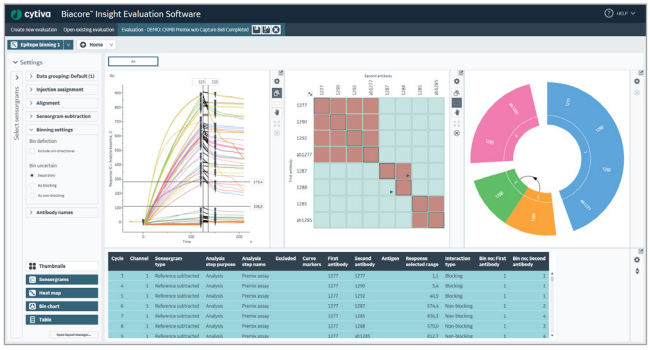


Fig 10. Sensorgram overlay, sorted heat map, and bin chart are central features of Biacore Insight Epitope Binning Extension for visualization and analysis of epitope bins.

Confident concentration and potency analysis

Biacore Insight Concentration and Potency Extension facilitates reproducible and robust concentration determinations of biologically active protein, not the total protein amount that would be obtained from an A280 determination.

The software enables seamless determination of drug potency and parallel line analysis (PLA) without the need for tedious data import or export between different softwares. The precision and automation of the system reduces hands-on time and generates highly reproducible data over a wide dynamic range with coefficient of variation (CV) typically below 5%, for Biacore T200, Biacore S200, Biacore 8 series and Biacore 1 series SPR systems.

The software supports both parallel (only valid for Biacore 8 series systems) and serial run modes, allowing you to select the optimal assay setup based on your needs. Calibration curves may be generated using four-parameter or linear-fitting models. The software supports evaluation of the samples using single and average calibration curves. For long runs in serial mode, interpolation of calibration curves to compensate for drift in the assay may be performed to generate highly reliable data.

The possibility to include control samples allows you to ensure rigorous quality control for your assay. Drug product amount and activity are reliably determined using surrogate potency assays — reducing cost and saving time.

Potency assays can be easily evaluated using the built-in software tools of Biacore Insight Concentration and Potency Extension. This allows you to determine the potency of your sample relative to a reference sample, streamlining the analysis workflow and lowering the risk for user mistakes and data manipulation when transferring data between different software. Potency analyses are performed using PLA or half-maximal response (EC50) determinations. The PLA functionality makes the assessment of potency based on a linear fit to the linear part of the response vs logarithmic concentration assuming a common slope (Fig 11). The EC50 determination is based on a four-parameter equation being fitted to the response versus concentration.

- Determine active protein concentration with confidence, shortening your time to results with automation and minimum hands-on time.
- Reliably determine drug product amount and activity using surrogate potency assays, reducing cost, and saving time.
- Increased assay precision and reproducibility over a wide dynamic range.
- Eliminate errors in data transfer with built-in parallel line analysis tool.
- Sample purposes: channel normalization and calibration. A dilution variable for built-in calculation of the concentration in the original undiluted samples.

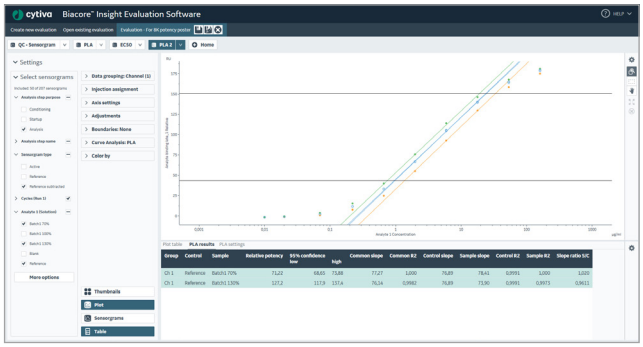


Fig 11. Evaluation of potency data using tool for ***Parallel line analysis***.

Compliant GxP regulated environments

An optional Biacore Insight GxP Extension allows Biacore 1 series and Biacore 8 series systems to integrate seamlessly into GxP regulated workflows. The software extension provides validated software supporting GLP, GCP, GMP, and 21 CFR Part 11 compliance and includes validation support. The software has been developed in accordance with an accepted development model to ensure adequate validation. For full validation support of the system, the software extension can be supplemented with Cytiva's OptiRun™ Qualification Service.

Features in the GxP extension include:

- Data integrity — access control and enforced version handling.
- User authorization levels — administrator, developer and user levels set access rights to software functions.
- Procedures for operational control — enables assay run and evaluation settings to be locked together in routine assays.
- Audit trail — tracks record modifications and maintains complete version histories for published procedures.
- eSignatures for new procedures and finished evaluations.

Streamlined transfer of SPR data between instruments and different labs

The flexible result export feature in Biacore Insight Software lets you easily export selected or comprehensive data for continued processing, result reporting, or storage.

You can export data in Microsoft Excel, PDF, and Microsoft PowerPoint format. Simply select the ***Presentation*** option under ***Export*** to in the ***Home*** space to select evaluation items and export them as native presentation charts and tables. From there, you can modify your data using the extensive tool set and layouts in the presentation application, making it easy to share data with your colleagues and peers.

Additional export options are enabled by Biacore Insight Data Integration Extension. Allowing you manual export in the machine-readable JSON format as well as access to Biacore Insight API for fully integrated and automated data transfer to LIMS, ELN, or other third-party software (Fig 12).

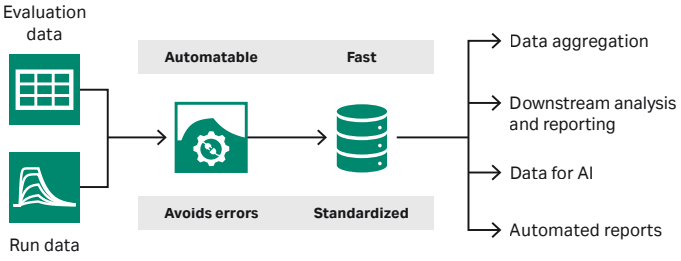


Fig 12. Application programming interface enabled by Biacore Insight Data Integration Extension. Allows for fully automated data export.

Full control of all your data supported through Biacore Insight database

Biacore Insight database is the central storage space for all your runs, evaluations, and methods. It enables full control of all your data while improving data safety and integrity compared to file-based systems. Never lose track of results again. By searching within results, you can determine who, when and where an experiment was run.

- Efficient — multiple users can access the data at the same time, and edits are reflected immediately.
- Safe — convenient backup option and user access control, ensuring data integrity.
- Searchable — managing your data has never been easier. Search your data to find runs from a single user, instrument, ligand, or sample name.
- Fast — database operations and evaluations of vast amounts of data are faster than on a file-based system.
- Action history — easily follow up on experiments, maintenance routines and service visits. All accessible via the convenient database search and filter tools.

Minimize cost using shared software access rights

Biacore Insight Software uses floating licenses, that allow sharing of access rights between users and computers and removes restrictions on the number of simultaneously installed copies of the software. The floating e-licenses enable large groups of users to access and benefit from software extensions, while minimizing cost. In addition, time-limited licenses are available, allowing you to flexibly scale the number of licenses to your needs. The license distribution is managed by our Software Licensing Manager.

Technical specifications

Computer requirements

- 64-bit Microsoft Windows 10 Enterprise or Professional (English). 64-bit Microsoft Windows 11 Enterprise or Professional (English).
- CPU with at least four cores, 2 GHz or faster.
- At least 16 GB internal memory.
- At least 200 GB free hard disk space.
- Screen resolution of at least 1920×1080.
- One USB2 port available for instrument connection.

Database

Biacore Insight Software includes SQL Server Express 2019. Performance improvements are seen with SQL Server Standard, SQL Server Enterprise, or SQL Data Warehouse version 2017 or 2019 (available separately from Microsoft).

Contact your local Cytiva representative for full technical specifications.

Table 1. Biacore Insight Software tailored for Biacore 1 series, Biacore 8 series, Biacore T200, and Biacore S200 systems

	Biacore 1 series systems	Biacore 8 series systems	Biacore T200 system	Biacore S200 system
Biacore Insight Evaluation Software	✓	✓	✓	✓
Biacore Insight Control Software	✓	✓		
Biacore Insight Extended Screening Extension	✓	✓	✓	✓
Biacore Intelligent Analysis Software	✓	✓	✓	✓
Biacore Insight Epitope Binning Extension	✓	✓	*	*
Biacore Insight Concentration and Potency Extension	✓	✓	✓	*
Biacore Insight GxP Extension	✓	✓		
Biacore Insight Data Integration Extension	✓	✓	✓	✓

* Biacore Insight Software and software extensions support data evaluation.
The instrument specific control software does not contain dedicated application support but does have all necessary functionalities.

Ordering information

	Software	Extensions					
Product and license type	**Biacore Insight Software**	**Biacore Insight Extended Screening**	**Biacore Intelligent Analysis**	**Biacore Insight Epitope Binning**	**Biacore Insight Concentration and Potency**	**Biacore Insight Data Integration**	**Biacore Insight GxP**
Permanent, 1-pack	29310602	29310610	N/A	29478580	29332204	29478588	29332212
Permanent, 5-pack	29310603	29310611	N/A	29478581	29332205	29478589	29332213
Permanent, 10-pack	29310604	29310612	N/A	29478582	29332206	29478590	29332214
1-year, 1-pack	29310606	29310614	29714150	29478584	29332208	29478592	29332216
1-year, 5-pack	29310607	29310615	29714151	29478585	29332209	29478593	29332217
1-year, 10-pack	29310608	29310616	29714152	29478586	29332210	29478594	29332218

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