Biacore™ Insight Software

LABEL-FREE INTERACTION ANALYSIS

Biacore™ Insight Software streamlines the entire SPR workflow. From run to insight, the software enables fast, intuitive run setup, data analysis, and data integration to reduce time to results regardless of user experience or instrument model (Fig 1). Biacore Insight Software supports affinity and kinetics analysis with reliable determination of equilibrium binding constants and kinetic rate constants. This is achieved with predefined evaluation methods that include built-in fitting support and quality indicators. These core applications provide fast screening level assessments and in-depth characterization of individual interactions.

The software also has flexible plotting and visualization tools, including sensorgram overlays, result tables, and plots so you can simultaneously inspect raw data, fitted curves, and key parameters. This integrated and customizable visualization environment supports rapid data qualification, comparison, and confident interpretation of results.

The modular, flexible design easily switches between application specific software tools and extensions for screening, affinity, kinetics, concentration, potency, sensorgram comparison, and epitope binning to supporting evolving research needs at any stage.

Optional 21 CFR Part 11 support provides seamless integration into regulated workflows when required.

Biacore Insight Software 7.0 introduces key advancements designed to support confident decisions and streamlined collaboration in modern biotherapeutic development. At its core, the reintroduced ***Sensorgram comparison*** tool enables regulatory-ready comparability assessment by objectively quantifying sample similarity against a reference standard, leveraging the full information content of sensorgrams rather than relying on single metrics. Complementing this, enhanced data sharing capabilities allow users to export anonymized, password-protected datasets, facilitating secure collaboration across teams and sites. In addition, the integrated application programming interface (API) supports automation of workflows, enabling efficient sample preparation based on saved methods and improving consistency across experiments. Together, these updates accelerate time to reliable conclusions while ensuring data integrity, reproducibility, and compliance.

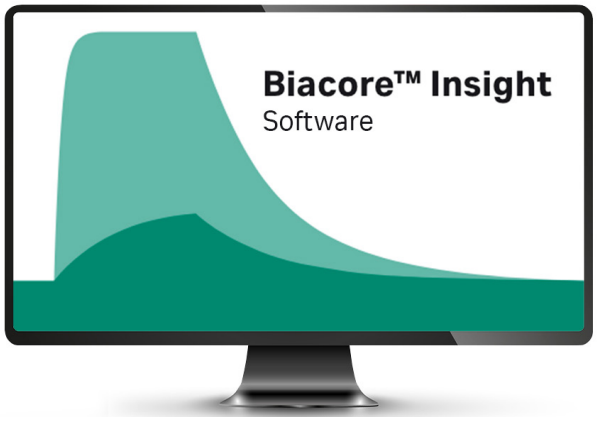


Fig 1. Biacore Insight Software, the unified platform for efficient instrument control and data evaluation across Biacore 1 series and Biacore 8 series SPR systems.

SPR streamlined from run to insight

- **Unified and robust platform** to run, analyze, and visualize SPR data faster. Reduce time to reliable conclusions with data consistency and quality.
- **High-quality affinity and kinetics analysis** for reliable determination of equilibrium binding constants and kinetic rate constants. Uses predefined evaluation methods with built-in fitting support and quality indicators.
- **Scalable versatility** through application-specific extensions lets users tailor the platform to evolving workflows, applications, and regulatory requirements.
- **Evaluate SPR data in minutes** with pretrained machine learning models included in Biacore Intelligent Analysis™ software.
- **Seamless data export** for customized, publication ready results.
- **Optional 21 CFR Part 11 support** for integration into GxP-regulated workflows.

Biacore Insight Software components

Biacore Insight Software provides consistent workflow for SPR experiments, from run setup to data evaluation and reporting. The sections below describe what is included in the software and how optional extensions can be added to support specific applications and regulated workflows.

Our software consists of:

- **Biacore Insight control software:** Predefined run methods cover a wide range of applications. Provides guidance and support for assay setup, with changeable settings for sample run order, control intervals, and sample concentrations.
- **Biacore Insight evaluation software.** Analyze your data with just a few clicks. Capable of rapid analysis of large screening campaigns, deep kinetic characterization of a single interaction, epitope binning experiments, or reproducible quantitation of samples.
- **Biacore Insight database.** Provides full control of your data. Improves data safety and integrity compared to file-based systems.
- **Biacore Insight API server.** Enables automated integration of Biacore SPR system data into your lab's information management system via an API.
- **Cytiva software licensing manager.** Provides floating licenses that share access rights between users and computers. Removes restrictions on the number of simultaneously installed copies of software

Biacore Insight control software

Biacore Insight control software is the unified instrument control for Biacore 1 series and Biacore 8 series systems. The adaptable, predefined methods come with application-relevant, pre-settings available for all major assays. The intuitive, easy to use interface, enables quick setup of experiments quickly.

The ***Activity queue*** lets you stack operations, which minimizes unnecessary waiting times and maximizes throughput (Fig 2). 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 has additional features for easy transfer of methods between instruments.

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 SPR scientists and engineers provide standardized, simplified data analysis that helps you avoid repetitive tasks. Use them as is, or as a template for your optimized user-defined evaluation methods.

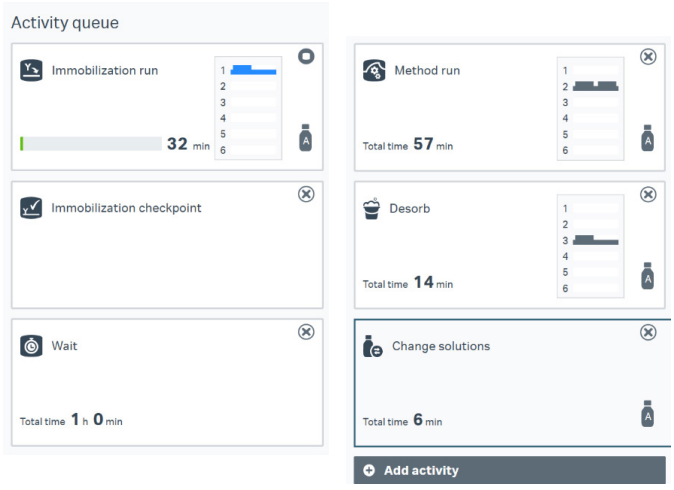


Fig 2. The ***Activity queue*** shows immobilization and run methods as well as maintenance routines queued up for processing by a Biacore system.

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 your experiment and provide results you can trust. The evaluation interface can be configured to maximize space for your most important tasks at any time (Fig 3):

- 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.

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

Fig 3. The flat interface of Biacore Insight evaluation software provides a full overview and flexible tools for customized data analysis. The overview provides convenient simultaneous visualization of kinetics and affinity data including ***Result table***, ***On-off rate chart***, and **K_D chart**.

Regulatory-ready comparability assessment

Biacore Insight Software and ***Sensorgram comparison***, Cytiva's patented approach to objectively measure sample similarity, utilizes the full information content in sensorgrams.

Comparison of binding data is a critical step in late-stage development and manufacturing quality control of biotherapeutics as well as in biosimilar development where products are assessed against an originator. In both cases it is essential to understand and monitor any changes in target binding activity during product development or process modifications to safeguard drug safety and efficacy.

While kinetic fitting and report-point analysis are commonly used, these approaches can become challenging or insufficient when binding behavior is complex. This is often the case for next generation biologics such as Fc-fusion proteins, bispecific antibodies, and antibody drug conjugates.

Sensorgram comparison simplifies comparability assessments by objectively comparing complete binding profiles of samples against a reference standard. Support for multiple injections enables simultaneous evaluation of several critical quality attributes within a single sensorgram, allowing quantitative comparisons of simple and complex binding data. The resulting ***Similarity score*** allows samples to be ranked based on relative binding similarity. Reference standards can be saved within evaluation methods, making ongoing batch-to-batch comparison straightforward by applying predefined standards and settings to new samples (Fig 4).

1. Establish standard limits

- Limits can be adapted to the assay variations you want to track.
- Limits are saved within evaluation methods.

2. Run the samples

- Include both positive and negative controls to verify assay consistency.
- Use same assay parameters as for the standard.

3. Directly assess comparability

- Objective comparison of direct binding profiles. No curve fitting and report point analysis.
- A single similarity score capture the comparability.
- Visualization helps spotting difference and acting on them.

Fig 4. From standards to similarity score: three streamlined steps to comparability assessment you can trust across development and quality control.

The ***Sensorgram comparison*** tool within Biacore Insight evaluation software contains various settings that enable you to define the best similarity range for each assay. By setting an acceptable similarity limit the system automatically accepts or rejects samples (Fig 5).

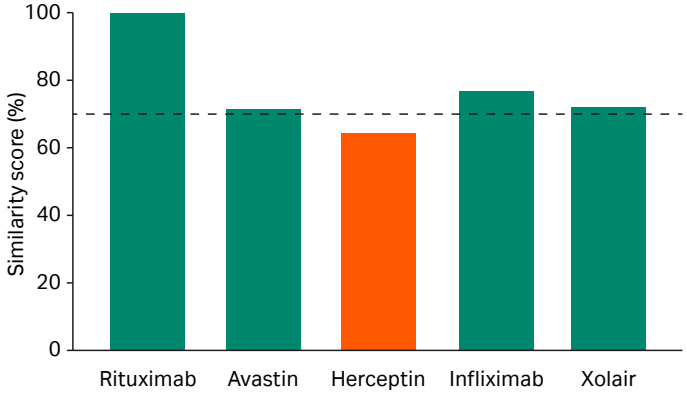


Fig 5. Bar chart showing the similarity scores of different biosimilars. Acceptance threshold was set to 70%. Any sample below this threshold is automatically rejected.

The deviation chart supports identification of deviations to guide further assay development and process changes to reach the desired similarity score (Fig 6).

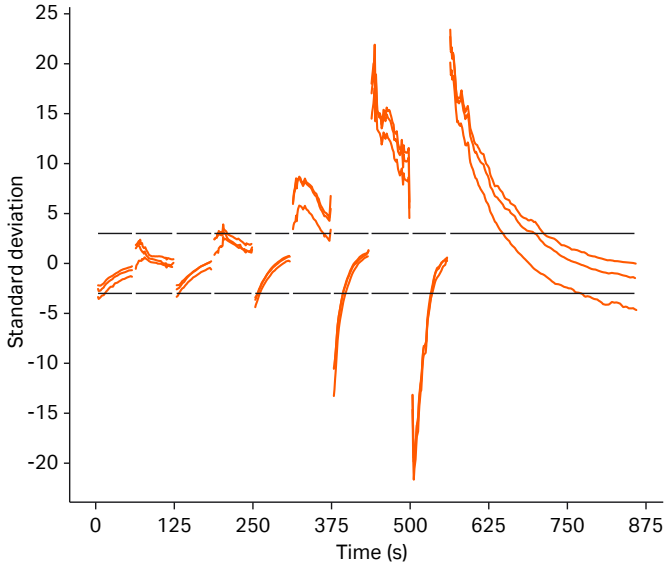


Fig 6. Deviation chart for a sample with deviations from the reference material at higher concentrations in single cycle kinetics.

Expand capabilities with application-specific extensions

The core functionality of the SPR software can be expanded with application specific software extensions that address analytical needs with a unified workflow and user experience:

- **Biacore Insight extended screening extension:** accelerated screening workflows with additional tools for single concentration screening as well as affinity and kinetics. Provides predefined run and evaluation methods to streamline screening-based interaction studies for rapid hit identification and prioritization while reducing assay setup and evaluation time.
- **Biacore Intelligent Analysis™ software:** automated and consistent analysis of large SPR data sets. Machine learning–based evaluation support for binding level and affinity screens that reduce manual data curation and improve consistency across large screening campaigns.
- **Biacore Insight epitope binning extension:** efficient identification and visualization of epitope diversity. Dedicated support for epitope binning experiments, including automated data evaluation and intuitive visualization of blocking relationships to simplify assay development and interpretation.
- **Biacore Insight concentration and potency extension:** robust determination of active concentration and potency. Supports reproducible determination of active protein concentration and potency using parallel line analysis (PLA) and EC50 evaluation with minimal manual data handling.
- **Biacore Insight data integration extension:** seamless integration of SPR data into digital workflows. Enables export of SPR data in machine readable formats and access to Biacore Insight API for integration with LIMS, ELN, and other third party systems.
- **Biacore Insight GxP extension:** regulatory support for GxP regulated environments. Adds functionality to support workflows governed by GLP, GCP, GMP, and 21 CFR Part 11 requirements, including access control, audit trails, and electronic records and signature.

The optional **Biacore Insight extended screening** extension contains features that shorten time to result for the entire SPR workflow drug discovery screening workflow

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

- ***Clean screen:*** efficiently clean up low molecular weight (LMW) and fragment libraries. Easily identify sticky, residual binders to the sensor chip surface to minimize the risk of false negatives.
- ***Binding level screen:*** 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:*** 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 to deliver key insights in the sensorgram data, making it faster and easier to filter out false positives (Fig 7).

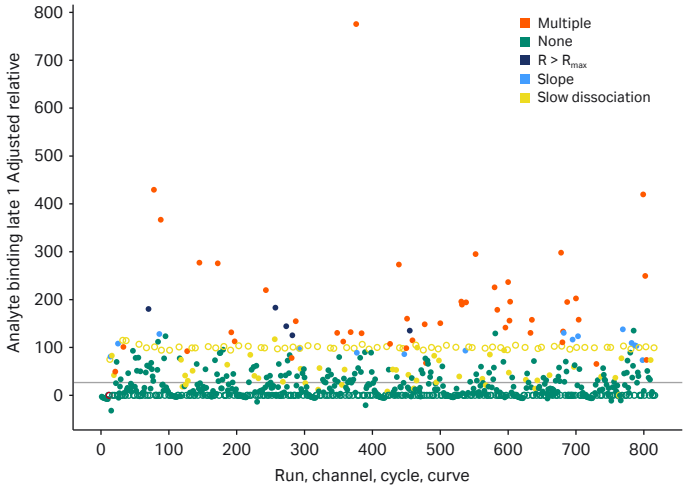


Fig 7. Plot of fragment screen results are analyzed with binding behavior markers. The automatic evaluation marks the samples. Settings can be adjusted for how sensitive the automatic evaluation applies these markers.

Guidelines throughout the visualizations enhance your understanding of the data and provide additional information (Fig 8). Guideline curves in ***Plot*** enhance first look evaluation capabilities by adding reference surface sensorgrams and ideal fragment shape profiles. Guidelines in ***Affinity*** 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 screen*** and first pass screens.

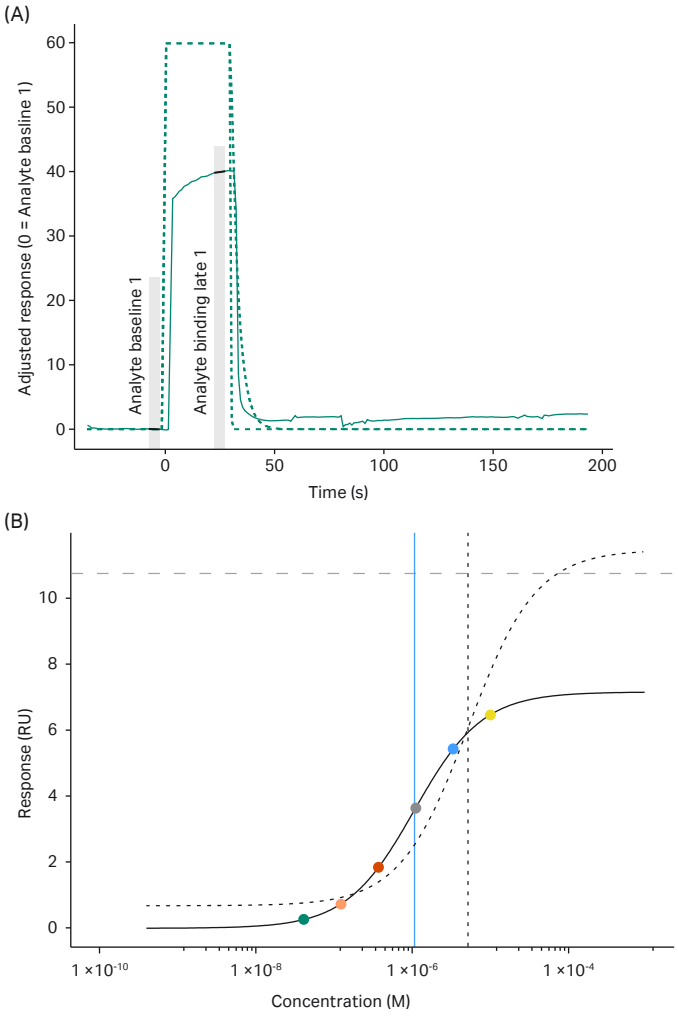


Fig 8. (A) selecting any point in a plot item will display the corresponding sensorgram data. Additional guidelines can be activated to show ideal fragment shape and the reference surface sensorgram. (B) Affinity plot showing the constant R_{max} fit line together with the free fit. Vertical lines for K_D values and a horizontal line for the expected R_{max} help in your evaluation process.

Reduce the analysis bottleneck in binding level and affinity screens

Biacore Intelligent Analysis™ software enables consistent and automated analysis of large data sets by significantly reducing the manual, time-consuming steps of data curation and quality control. This optional extension supports 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 created by our scientists that provide a ready to go solution for fragment binding level and affinity screening data analysis. They are validated for greater than 90% accuracy as opposed to human expert analysis and have 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 features:

- ***Binder prediction quality*** automatically predicts the quality of the interaction (high, low, or uncertain).
- ***Binder prediction classifications*** are automatically applied so the user can 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 9).

Fig 9. ***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 manage 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 manual 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 for further characterization of the interaction and sets 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 10).

Fig 10. Fragment ***Affinity screen*** analyzed by Biacore Intelligent Analysis software.

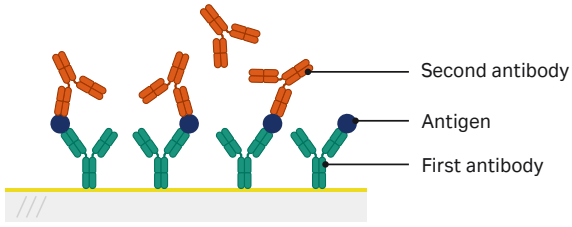
Anything the prediction models created can be overwritten and assigned your own analysis at any time. To make changes to the prediction model, simply select ***Train new version***. The prediction models you create (from blank or naive models or by retraining the prediction models) can be managed, tracked, and annotated in the prediction model manager. When a prediction model is established, you only need to assess the few ***Uncertain*** samples, which reduces the evaluation effort by up to 80%. You also have the option to import or export prediction models to share between collaborators and drive standardization in your analyses, 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 immediate functionality.
- Option to further train prediction model over time using your own data, or start with an untrained, naive model.
- Prediction model manager allows the user to import, export, track, and manage prediction model versions.

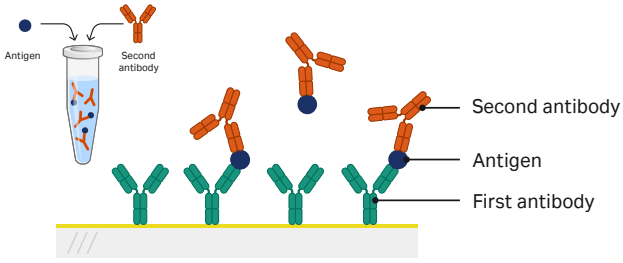
Rapid overview of epitope diversity to identify and maintain unique protein binding sites

Biacore Insight epitope binning extension delivers automated identification of unique, diverse, and effective epitopes that help broaden intellectual property protection. The optional extension provides support from run setup 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 from Biacore T200, Biacore S200, Biacore 8 series and Biacore 1 series SPR systems (Fig 11). To minimize assay development time there is also an option to use capture format with and without blocking step (See Application guide epitope binning)

Sandwich assay



Premix assay



Tandem assay

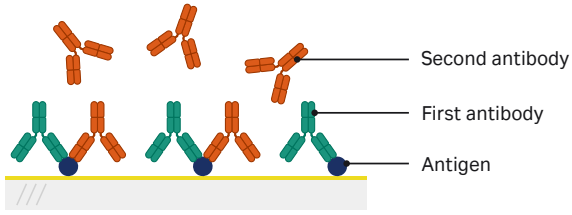


Fig 11. Three different assay formats to run epitope binning experiments, all supported by Biacore Insight Software.

One challenge in epitope binning is the scenario when low affinity binding between the antigen and first antibody leads to dissociation of the antigen. This results 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 (Fig 12).

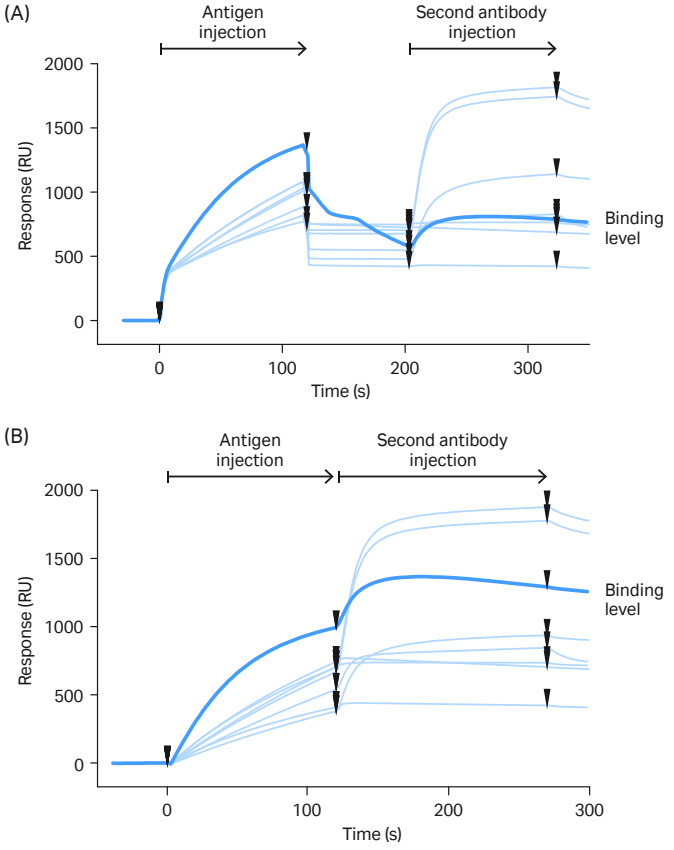


Fig 12. ***Dual*** command minimizes the dissociation of antigen before the second antibody is injected, facilitating data interpretation. (A) Weak interaction between first antibody and antigen may lead to underestimation of second antibody level. (B) ***Dual*** command enables interpretation of fast 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. Heatmaps provide a rapid overview of blocking, non-blocking, and uncertain antibody pairs. This allows for straightforward inspection of data in the heat map and easy adjustments of cut-offs in the corresponding sensorgram.

Additionally, the bin chart provides an intuitive and easy approach to illustrate and visualize epitope diversity. Different bins containing corresponding antibodies are displayed in distinguishable colors. Clusters of overlapping bins are separated by gaps and 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 automatic analysis and visualization of bins (Fig 13). All visualizations are dynamically updated when thresholds or settings are changed.

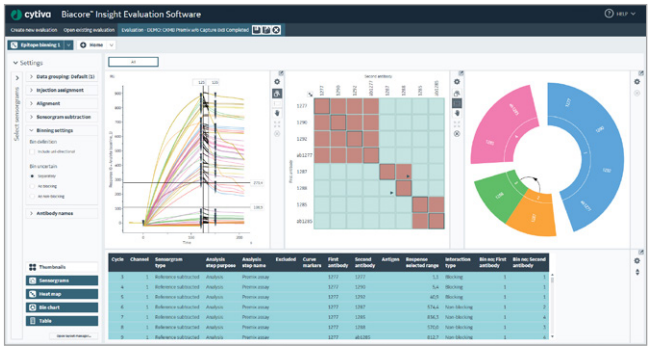


Fig 13. Sensorgram overlay, sorted heat map, and bin chart are central features of Biacore Insight epitope binning extension for visualization and analysis of epitope bins.

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 delivers seamless determination of drug potency and PLA without the need for tedious data import or export between different software. The precision and automation of the system reduce hands-on time and generate highly reproducible data over a wide dynamic range with coefficient of variation typically below 5% for Biacore T200, Biacore S200, Biacore 8 series and Biacore 1 series SPR systems.

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

The possibility to include control samples provides 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 easily be evaluated using the built-in software tools of Biacore Insight concentration and potency extension to determine the potency of your sample relative to a reference sample. This streamlines the analysis workflow and lowers 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 14). The EC50 determination is based on a four-parameter equation being fitted to the response versus concentration.

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

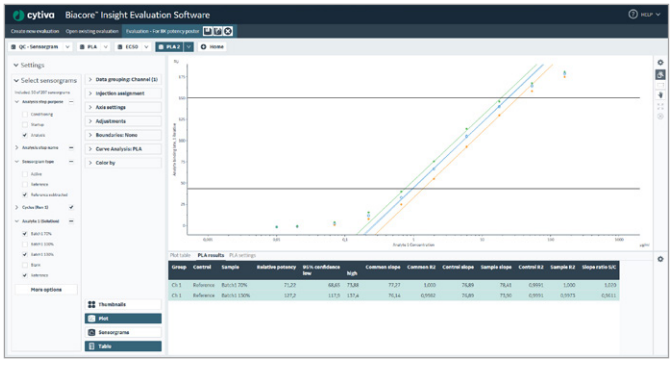


Fig 14. Evaluation of potency data using the ***Parallel line analysis*** tool.

GxP support for regulated environments

Biacore Insight GxP extension is an optional software addon for Biacore 1 series and Biacore 8 series systems, designed to support work in GxP regulated environments. It enables the use of Biacore Insight Software within workflows governed by **GLP**, **GCP**, **GMP**, and **21 CFR Part 11** requirements.

The extension provides software functionality intended to support regulatory compliance including controlled access, traceability, and electronic records and signatures. The software has been developed in accordance with an accepted development model to support system validation and includes validation support documentation.

For customers requiring full system qualification, the GxP extension can be complemented with **Cytiva's qualification service**. Key features of Biacore Insight GxP extension include:

- **Data integrity** through access control and enforced version handling.
- **User authorization levels**, with administrator, developer, and user roles controlling access to software functions.
- **Operational control procedures**, enabling assay run and evaluation settings to be locked together for routine use.
- **Audit trail functionality**, tracking record modifications and maintaining complete version histories for published procedures.
- **Electronic signatures** for new procedures and completed evaluations.

Streamlined transfer of SPR data between instruments and different labs

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

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

Additional export options are enabled by **Biacore Insight data integration extension**, which allows manual export in the machine-readable JSON format and access to Biacore Insight API for fully integrated and automated data transfer to LIMS, ELN, or other third-party software (Fig 15). Biacore Insight API allows you request plate layouts from saved methods to prepare with your automated liquid handling solutions as well as results and evaluations.

With Biacore Insight Software 7.0 it is now possible to anonymize exports for easier sharing of data with your application support. It also provides password protected exports for more secure sharing between collaborating labs and groups within a company.

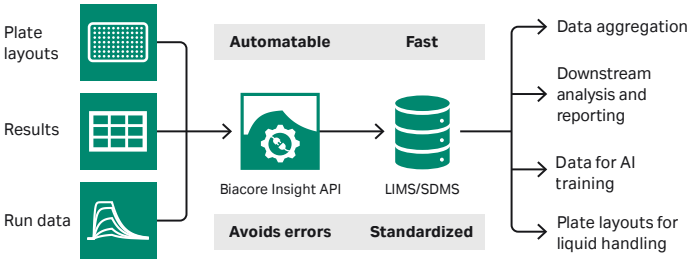


Fig 15. Application programming interface enabled by Biacore Insight Data Integration Extension. Allows for fully automated data export.

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 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. Edits are reflected immediately.
- Safe: convenient backup option and user access control for data integrity.
- Searchable: 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 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 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 2022. Performance improvements are seen with SQL Server Standard, SQL Server Enterprise, or SQL Data Warehouse version 2019 or 2022 (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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