

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 (Fig 1). It provides a streamlined approach to run, analyze, visualize, and export your 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.
- **Cytiva Software Licensing Manager**, that 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.

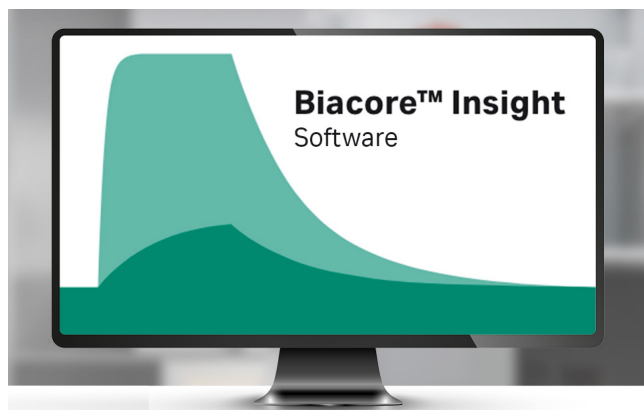


Fig 1. Biacore™ Insight Software provides a streamlined approach to run, analyze, visualize and export your SPR data.

- **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, improve visualization of your data.
- **Evaluate your data like the experts in minutes not hours** with Biacore Intelligent Analysis™: Machine learning models pretrained by Cytiva's Biacore™ experts 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 trails 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 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.

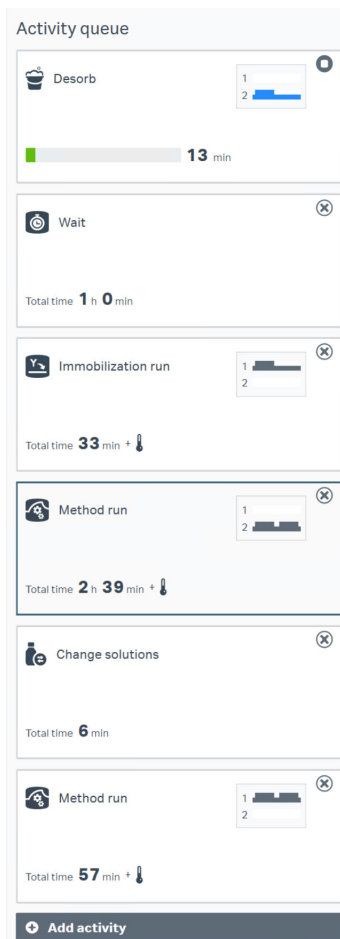


Fig 2. The **Activity queue** showing maintenance routines and methods queued up for processing by Biacore™ system.

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 Cytiva's Biacore™ scientists and engineers allow you to standardize, simplify data analysis and avoid repetitive tasks. Use them as is or as a template for your optimized user-defined evaluation methods.

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 for evaluation of single concentrations screens and affinity screens.

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

Included are predefined methods for running and evaluation screening experiments:

- **Clean screen** enables you to efficiently cleanup both 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/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 to the above run and evaluation methods, you can have adaptable binding behavior markers automatically annotate your screening results with the additional information provided in the sensorgram data making it faster and easier to filter out false positives (Fig 4).

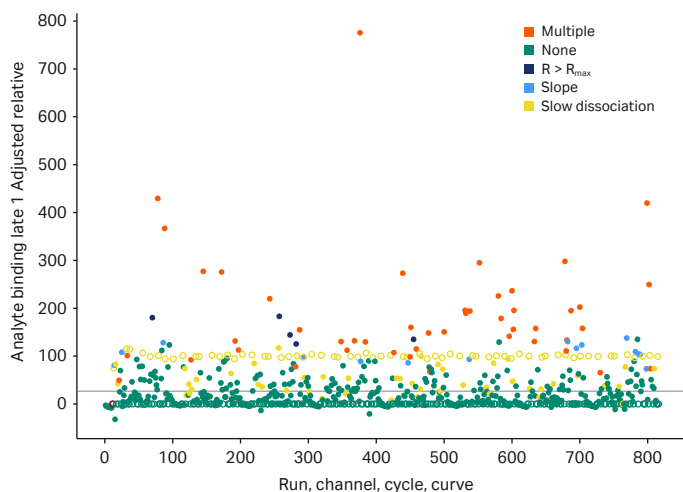


Fig 4. Plot of fragment screen results analyzed with binding behavior markers. The automatic evaluation marks the samples. The settings for how sensitive the automatic evaluation is can be adjusted by the user.

New 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 through-put for applications like **Clean screens** and first pass screens.

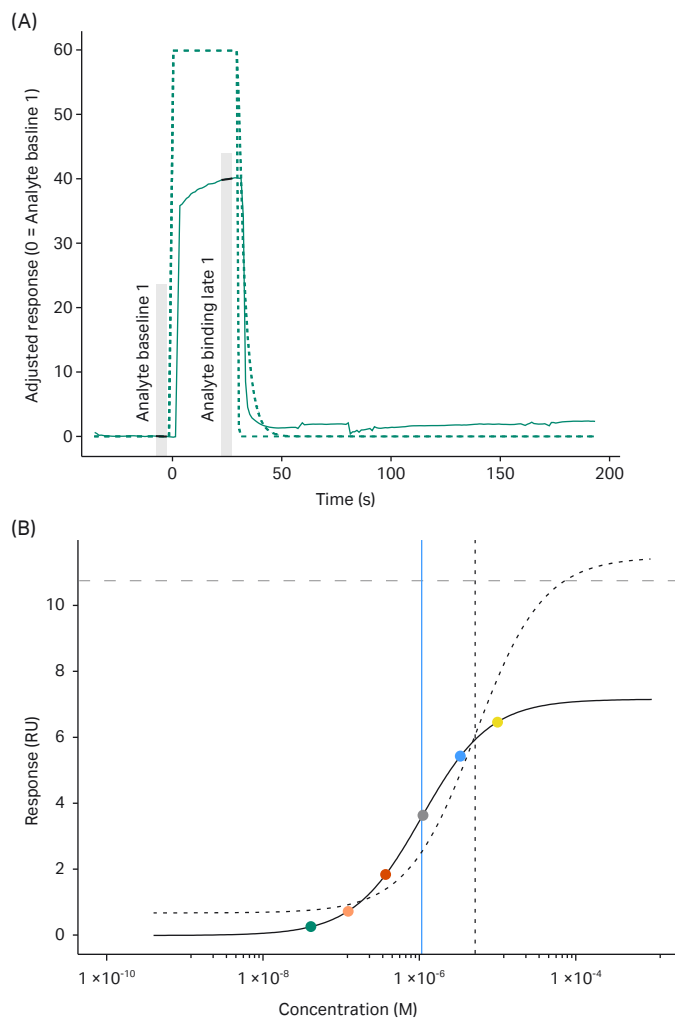


Fig 5. (A) selecting any point in a plot item will open up the corresponding sensorgram data. Additional guidelines can be activated to show ideal fragment shape and the reference surface sensorgram. (B) Affinity plot showing the constant R_{max} fit line together with the free fit. Vertical lines for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

Significantly reduce the analysis bottleneck in fragment screening applications using supervised machine learning software, Biacore Intelligent Analysis™

Biacore Intelligent Analysis™ enables the rapid 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 currently offers support for two analysis types, **Binding level screen** and **Affinity screen** for fragments from Biacore™ T200, Biacore™ S200, Biacore™ 8 series and Biacore™ 1 series SPR systems.

Biacore Intelligent Analysis™ comes with evaluation methods including prediction models, pretrained by Cytiva's scientists. The prediction models provide a ready-to-go solution for analysis of fragment binding levels and affinity screening data sets. They are validated to provide greater than 90% accuracy as opposed to human expert analysis with excellent sensitivity (> 87%) and specificity (> 90%). Run your fragment **Binding level screen** or fragment affinity screening experiments as before. Then in Biacore™ Insight Evaluation Software apply Biacore Intelligent Analysis™ by choosing the relevant prediction option, selecting the **Prediction model** and the model version you wish to apply, followed by **Predict**. Another option is to apply an evaluation method that contains **Prediction**.

Biacore Intelligent Analysis™ for fragment **Binding level screen** applications, automatically analyzes and classifies your binding level data via a series of feature sets. **Binder prediction quality** automatically predicts the quality of the interaction (high, low, or uncertain). **Binder prediction classifications** are automatically provided for sensorgrams predicted to have low quality to allow the user to understand how the binder prediction quality was reached and trace that prediction back to the underlying sensorgram data. **Binder prediction certainty** is a percentage measure of how confident the model is in the prediction of binder prediction quality (Fig 6).



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

Biacore Intelligent Analysis™ for fragment **Affinity screen** verifies target binding and automatically provides an estimate of steady state affinities. The prediction model automatically analyzes and assigns data into 3 categories accepted, rejected, or uncertain based on a series of features where each concentration series receive classifications that enable use of an appropriate steady state affinity model and provide the basis for accept and reject status. An acceptance certainty is calculated and shows how confident the model is in the prediction. In addition to these predictions, the prediction model will also automatically exclude deviant or outlier cycles from the affinity analysis prior to the prediction (Fig 7).

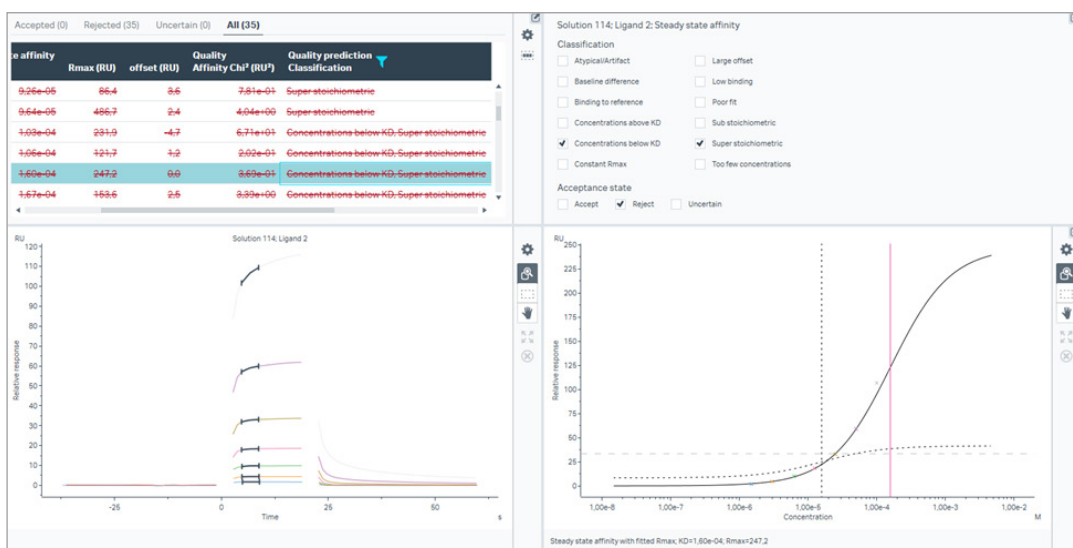
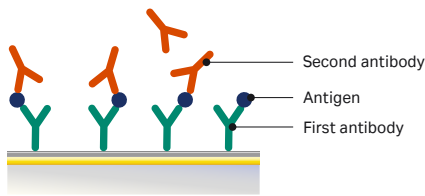
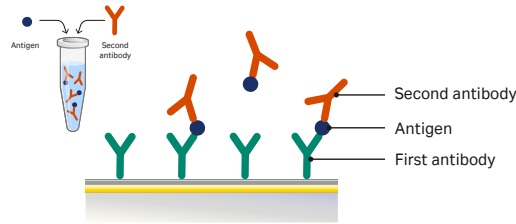


Fig 7. Fragment **Affinity screen** analyzed by Biacore Intelligent Analysis™ software.

Sandwich assay



Premix assay



Tandem assay

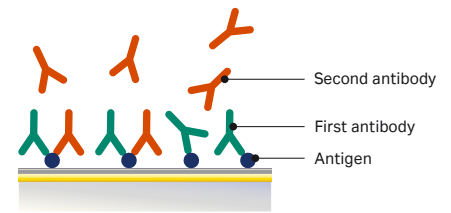


Fig 8. Three different assay formats to run epitope binning experiments, all supported by Biacore™ Insight Software.

You can override predictions that any of the prediction models have made and assign your own analysis to the data by checking or unchecking the option boxes at any time. To make changes to the prediction model simply select **Train new version**. The prediction models you create (either from the blank/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 models between groups and collaborators to 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 Cytiva's 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 site

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 pre-mix (Fig 8) from Biacore™ T200, Biacore™ S200, Biacore™ 8 series and Biacore™ 1 series SPR systems.

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).

A predefined evaluation method automatically processes data generated on Biacore™ 1 series, Biacore™ 8 series, Biacore™ T200 or Biacore™ S200 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, nonblocking and uncertain antibody pairs and allows for straightforward inspection of data in the heatmap, as well as easy adjustments of cut-offs in the corresponding sensorgrams.

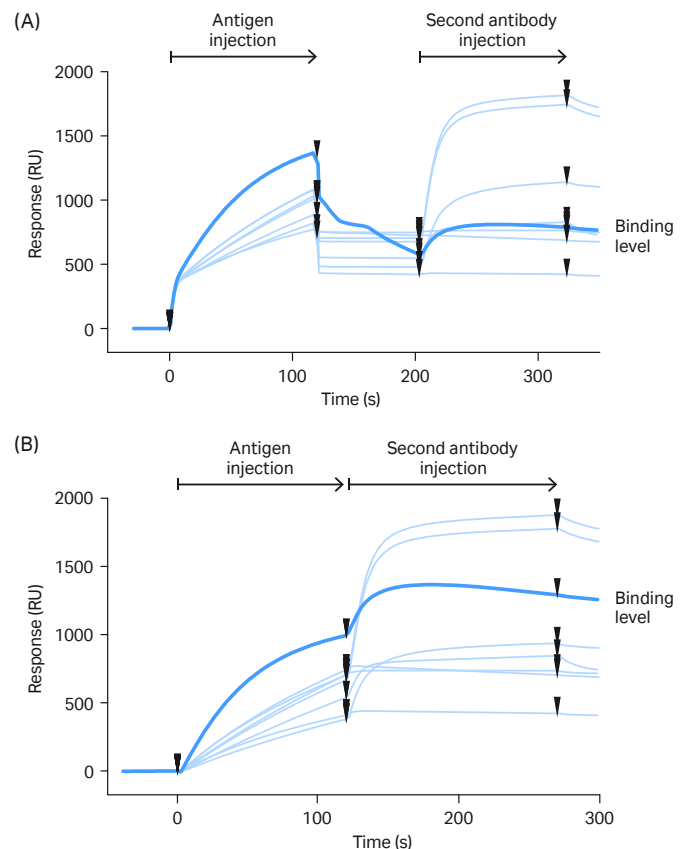


Fig 9. **Dual** command minimizes the dissociation of antigen before second antibody is injected, thus facilitates data interpretation. (A) Weak interaction between first antibody and antigen may lead to underestimation of second antibody level. (B) **Dual** command enables interpretation of fast dissociating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

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.

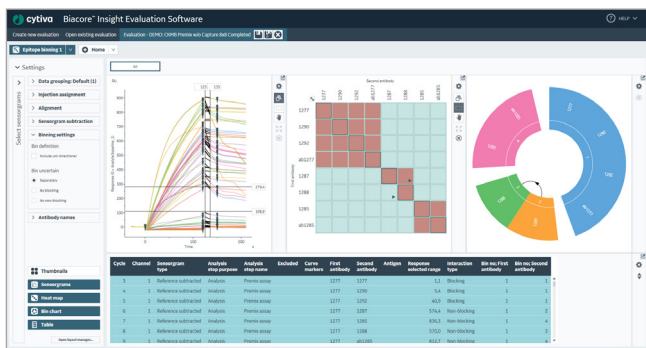


Fig 10. Sensorgram overlay, sorted heat map, and bin chart are central features of Biacore™ Insight Epitope Binning Extension for visualization and analysis of epitope bins.

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/export between different software. The precision and automation of the system reduces hands-on time and generates highly reproducible data over a wide dynamic range with CVs 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) 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 inbuilt calculation of the concentration in the original undiluted samples

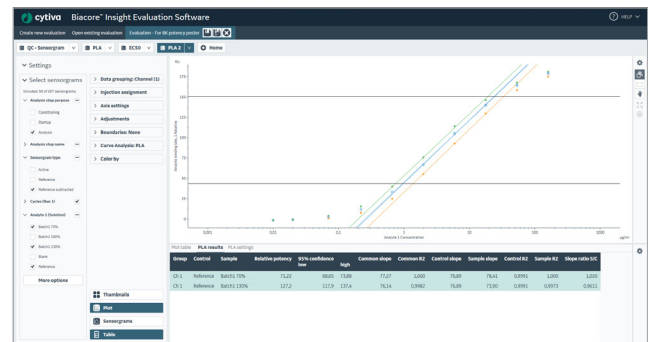


Fig 11. Evaluation of potency data using tool for **Parallel line analysis**.

Compliant GxP regulated environments

An optional Biacore™ Insight GxP Extension allows Biacore™ 1 series and Biacore™ 8 series 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 Evaluation Software lets you easily export selected or comprehensive data for continued data 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 available in Biacore™ Insight Data Integration Extension and enables export of data from Biacore™ 1 series, Biacore™ 8 series, Biacore™ T200, and Biacore™ S200 in JSON or XML format, both well-established standards for data exchange for integration to LIMS, ELN, or other third-party software.

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 group 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 the Cytiva Software Licensing Manager.

Technical specifications

Computer requirements

- 64-bit Microsoft Windows 10 Enterprise or 64-bit Windows 10 Professional, English versions.
- CPU with at least four cores.
- 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

	Biacore™ 1 series	Biacore™ 8 series	Biacore™ T200	Biacore™ S200
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/or extensions support data evaluation.
The instrument specific control software does not contain dedicated application support but does have all necessary functionalities.

Ordering information

Product	Software	Extensions					
	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 Single License	29310602	29310610	N/A	29478580	29332204	29478588	29332212
Permanent 5 License Pack	29310603	29310611	N/A	29478581	29332205	29478589	29332213
Permanent 10 License Pack	29310604	29310612	N/A	29478582	29332206	29478590	29332214
Permanent 20 License Pack	29310605	29310613	N/A	29478583	29332207	29478591	29332215
1 Year Single License	29310606	29310614	29714150	29478584	29332208	29478592	29332216
1 Year 5 License Pack	29310607	29310615	29714151	29478585	29332209	29478593	29332217
1 Year 10 License Pack	29310608	29310616	29714152	29478586	29332210	29478594	29332218
1 Year 20 License Pack	29310609	29310617	N/A	29478587	29332211	29478595	29332219

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