



## Label-free interaction analysis

# Biacore™ T200 Software v3.0

Biacore T200 Software v3.0 (Fig 1) offers confident quantitation of target binding similarities even for the most complex biologics. Novel evaluation tools extend the applicability of Biacore T200 system into the area of comparability and biosimilarity. In addition, the software provides you with improved and simplified evaluation tools for calibration-free concentration analysis (CFCA), support for Sensor Chip Protein A, and enhanced export functionalities.

- Assess comparability even for the most complex biologics
- Sensitive and reproducible determination of active concentration
- Quantitate biotherapeutic antibodies with Sensor Chip Protein A
- Conveniently customize and standardize export of selected data

Biacore T200 is an established surface plasmon resonance (SPR) instrument for which there are already validated and regulatory approved ligand-binding assays in use. By utilizing the sensitive and reproducible Biacore direct ligand-binding assay, you will confidently obtain the detailed characterization, comparability and, mechanism of action (MOA) data you need for new generation biologics (bispecific antibodies, antibody drug candidates, etc.) and that regulatory agencies require for CMC submissions.

## Comparability assessment with *Sensorgram Comparison*

Comparison of binding data is an important step in late-stage development and quality control (QC) of biotherapeutics. It is essential to understand and monitor any possible effect of target binding activity on product and process changes to ensure drug safety and efficacy. Kinetic and report point analysis is typically used but becomes challenging or even insufficient when the binding data is more complex, as is the case with new generation biologics such as Fc fusion proteins, bispecific antibodies, and diabodies.

Biacore T200 Software v3.0 makes comparability assessment easy by objectively comparing complete binding profiles of samples against that of a reference standard.

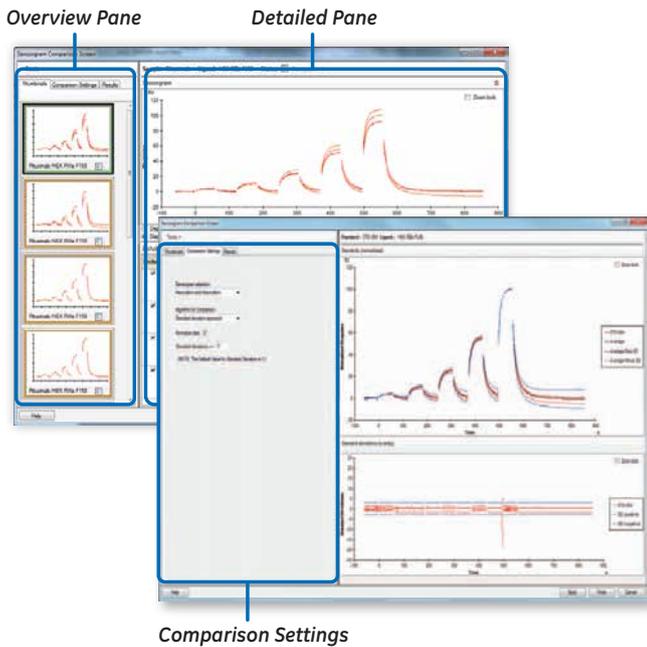


**Fig 1.** Biacore T200 Software v3.0 enables Biacore T200 with evaluation tools to allow biotherapeutic binding comparability assessment, CFCA analysis, support for Sensor Chip Protein A, as well as improved data export.

The ***Sensorgram Comparison*** tool enables quantitative comparisons of complex as well as simple binding data. With the resulting ***Similarity Score***, up to 100 sample data sets can be rated based on relative binding similarity. Result files from different runs can be appended enabling rapid co-evaluation of, for example, historical product batches. Co-evaluation and co-editing of results improves the quality of results, reduces the risk for user-mediated errors, and saves time by enabling the same adjustments and normalizations to take place.

A single display provides a holistic overview in a thumbnail pane while simultaneously giving details of the selected data series (Fig 2). Thumbnails in the ***Overview Pane*** enable rapid qualification of the data sets for the standard, control and samples, using color-coded frames for easy identification.

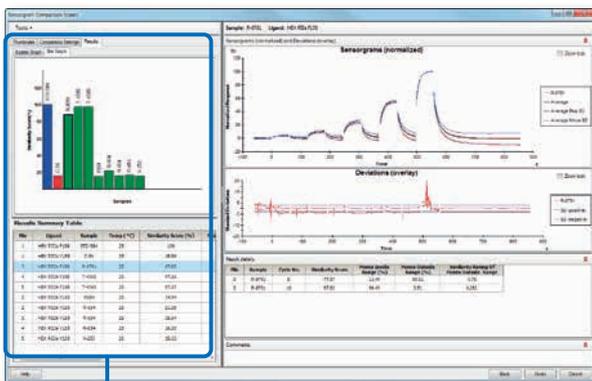
Data processing can be performed on all data series simultaneously and any data exhibiting bad binding behavior can be easily excluded. Tools are available for detailed editing such as cutting or rescaling of sensorgrams. All editing actions are clearly visualized in the ***Detailed Pane***, which also provides the possibility to qualify blank subtractions.



**Fig 2.** Good overview with fast access to detailed editing in the **Overview** and **Detailed Panes** simplifies data processing, giving rapid access to quality comparison results.

In **Comparison Settings**, evaluation criteria are conveniently set and instantly visualized in the **Detailed Pane**. Limits for the accepted assay variation are set using simple statistical tools such as standard deviation or min./max. algorithms. The comparisons can be performed on full sensorgrams, as well as association or dissociation phases.

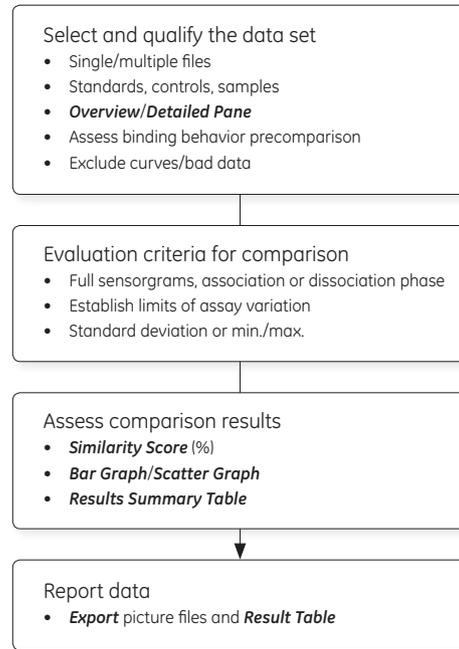
Results, including the **Similarity Score**, are summarized in the **Results Summary Table** and clearly displayed in a **Bar Graph** or **Scatter Graph** (Fig 3). Detailed inspection of individual sample results in the right-hand panel is facilitated by selecting individual samples in the summary table or graphs. Data may be sorted as well as commented with free text for optimal display and reporting.



Result summary with **Bar Graph**, **Scatter Graph**, and **Similarity Score** summary table

**Fig 3.** A clear overview of results for easier assessment of binding comparability data is given in the **Results Summary**.

The **Sensorgram Comparison** evaluation workflow is summarized in Figure 4.



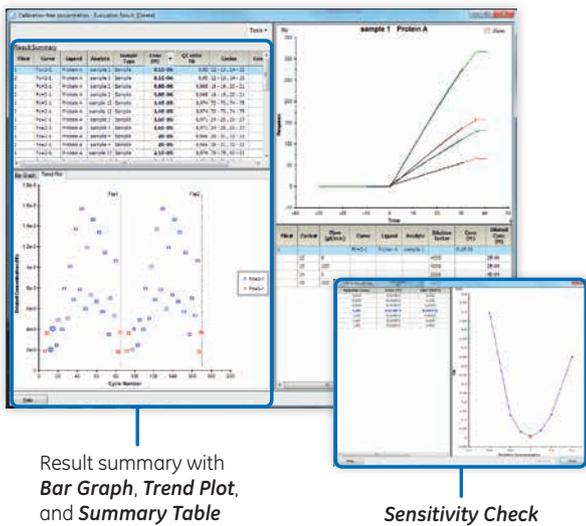
**Fig 4.** **Sensorgram Comparison** evaluation workflow.

## Reproducible concentration analysis without standards

In development and production of biotherapeutics, it is important to determine the concentration of functionally active molecules in a given sample as opposed to total concentration. In addition to traditional active protein concentration analysis using a calibration curve of known standards, the direct ligand-binding assay applied in Biacore T200 system supports determination of active concentration without standards by means of CFCA. Using CFCA allows determination of the protein concentration in unknown samples based on the diffusion properties of the protein, measured as the rate of binding to a target immobilized on the sensor surface under conditions of mass transport limitation.

Biacore T200 Software v3.0 facilitates reproducible and simple co-evaluation of more than 100 sample data sets from single or multiple runs. Rapid qualification and prefit selection of only relevant data speeds up the evaluation by minimizing the fitting time. **Global Fitting** of sample data improves the data fitting procedure and generates a single concentration value valid for a dilution series.

In **Results Summary**, fitted results are summarized in a table and simultaneously visualized in **Bar Graph** or **Trend Plot** overviews (Fig 5), for easy assessment of results. Data can be conveniently sorted and commented with free text.



Result summary with **Bar Graph**, **Trend Plot**, and **Summary Table**

**Sensitivity Check**

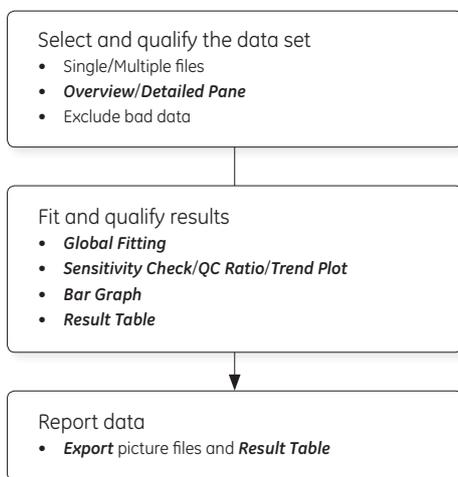
**Fig 5. Results Summary, Bar Graph, and Trend Plot** overviews allow easy assessment of CFCA results. Several dilutions of the same sample are globally fitted for robust evaluation.

The **Trend plot** provides full overview of samples and control samples against cycle number for better assessment of assay performance. Results from multiple runs are automatically separated by vertical lines.

In **Sensitivity Check**, the reliability of both the fitting procedure and the reported concentration can be assessed. **Sensitivity Check** complements other available QC tools (such as QC ratio,  $\chi^2$ , and standard error) for confident evaluation of generated results.

The CFCA algorithm relies on a known value for the diffusion coefficient of the protein, and direct access to a web-based Diffusion Coefficient Calculator tool is available in Biacore T200 Software v3.0.

The CFCA evaluation workflow is summarized in Figure 6.



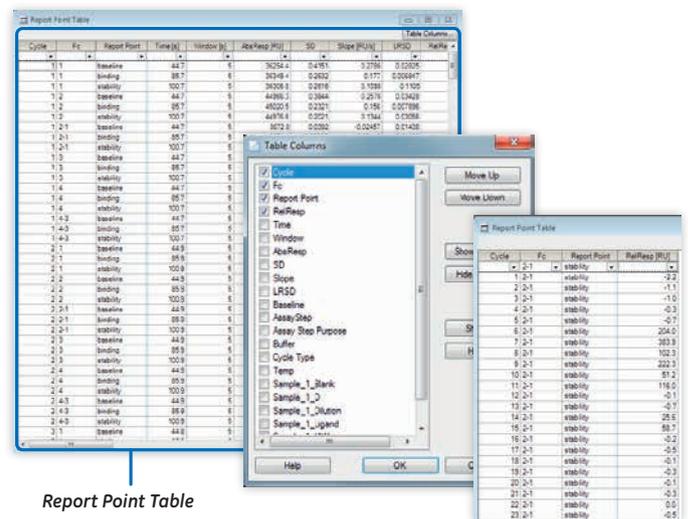
**Fig 6.** CFCA evaluation workflow.

## Data export

Biacore T200 Software v3.0 provides means to customize and standardize the export of the **Report Point Table** and the **Kinetic/Affinity** result table. The standardized export reduces the risk for user-mediated errors upon export to third-party software and saves time since it can be re-applied to new results files.

### Customization, reuse, and export of the Report Point Table

The **Report Point Table** lists numerical values for all report points in the current result set. Selection, sorting and filtering of the **Report Point Table** allows the user to focus on relevant results (Fig 7). All user-defined settings can be conveniently saved into an evaluation method and reapplied. The customized report point table can be exported to Excel® (XLS) and Excel macro (XLM) formats.



**Report Point Table**

**Fig 7.** Selection, sorting, and filtering of a **Report Point Table** allows a user to focus on relevant results.

### Export of results from Kinetic/Affinity

Results for **Kinetic/Affinity** are automatically displayed in a graph and a preset **Result Table**, ready for export. If needed, the user can sort and order results into a customized table, **Data for Export**, for storing of relevant results only. The customized table setting can be saved as a template and will be part of an evaluation method for the kinetic affinity item enabling a standardized export format.

## Data handling and storage

### PC operating systems

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Windows® XP Professional SP3  
Windows 7 Professional SP1, 64-bit  
Windows 8 Professional, 64-bit

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### Minimum computer requirements

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3.0 GHz processor  
RAM > 1 GB free  
CD-ROM drive  
Hard disk drive > 2 GB free  
Graphics resolution at least 1280 × 1024

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## Ordering information

Product	Code number
Biacore T200 Software v3.0*	29-1486-95
Biacore T200 GxP Software v3.0*	29-1486-99

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\*Includes software set, product key, and handbooks

Related products	Code number
Biacore T200 Processing Unit	28-9750-01
Biacore T200 GxP Package	28-9779-54
Biacore T200 Upgrade Kit	28-9779-54
Biacore T200 GxP Upgrade Kit	28-9779-64
Biacore T200 Software v3.0, additional license	28-9816-19

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Related literature	Code number
Brochure: When quality comes first. Cross new frontiers in label-free interaction analysis with Biacore T200	28-9794-12
Data file: Biacore T200	28-9794-15
Data file: Biacore T200 Upgrade Kit	28-9794-14
Datafile: Biacore T200 Software v2.0	29-0500-11
Data file: Biacore T200 GxP Package	28-9809-50
Application note: Biacore comparability tool for quantitating binding similarities in IgG Fcγ receptor analysis	29-1519-21
White paper: Biacore concentration and ligand binding analyses in late stage development and quality control of biotherapeutics	29-1480-54

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