Biacore™ Insight Software v6.0

Release Notes

1 Introduction

This document describes new functionality, improvements, and resolved issues in Biacore™ Insight Software version 6.0, compared to Biacore Insight Software version 5.0.18. Known remaining issues and limitations are also listed.

The main new features in version 6.0 are:

- Support for a new ***Inject and elute*** command for Biacore 1K+ and Biacore 1S+ systems.
- A broader use of Biacore Intelligent Analysis™, also for non-fragment compounds.
- Support for automatic export of run data and evaluated data via an Application Programming Interface (API).

Version 6.0 also includes improvements based on user feedback, defect fixes, and support for Windows 11 and SQL Server 2022.

Included software

This document describes Biacore Insight software, which consists of five separate components:

- Biacore Insight Control Software version 6.0
- Biacore Insight Evaluation Software version 6.0
- Biacore Insight Database version 2.3.1
- Cytiva Software Licensing Server version 5.1

- Biacore Insight API Server version 6.0 (optional)

Functionality

Biacore Insight Control Software supports set-up and execution of label-free interaction analyses with Biacore 1 series and Biacore 8 series instruments. The produced data is stored in a Microsoft SQL Server database, referred to as Biacore Insight Database.

Biacore Insight Evaluation Software provides a wide range of tools for evaluation of runs stored in Biacore Insight Database. Runs from Biacore 1 series and Biacore 8 series systems can be evaluated directly, whereas runs from older systems must first be imported to the database.

Biacore Insight Evaluation Software is provided as a basic package with optional extensions for specialized functionality. The basic software and extensions are licensed separately, and the licenses are managed by the Cytiva Software Licensing Server.

Biacore Insight API Server enables automated access to run data and evaluated data in the database for third-party applications.

Supporting documentation

For more information on functionality, see the following manuals:

- *Biacore 1 series User Manual (29706293)*
- *Biacore 8 series User Manual (29287247)*
- *Biacore Insight Evaluation User Manual (29287248)*
- *Biacore Insight GxP User Manual (29312548)*
- *Biacore Insight API Installation and Management Guide (29751155)*

Upgrade instructions

Upgrading from previous versions to 6.0 requires an update of the database. The installation and upgrade process is described in the following two manuals. The first contains information on a higher level and the second contains more detailed instructions:

- *Biacore Insight Installation and Upgrade instructions (29729572)*
- *Biacore Insight Database Guide Management Guide (29287249)*

Accessing software installers and documentation

Manuals, guides, instructions, software installers and release notes are available as follows:

- On *https://www.cytivalifesciences.com/support/software/Biacore-downloads*.
- As part of the software download package on Cytiva eDelivery, using a Biacore Insight activation ID FlexNet Login (flexnetoperations.com).

To be proactively informed about changes, subscribe to our change control portal: *https://www.cytiva.com/support/quality/regulatory-support/change-control-notifications*.

2 New functionality

The table below describes new functionality introduced in Biacore Insight Software version 6.0.

Software area	Description
Method builder	New ***Inject and elute*** command available for Biacore 1K+ and Biacore 1S+. The command is intended for studies of unknown, bioactive binders in a complex mixture. The bound analyte is recovered and can be further analyzed with other techniques.
Sensorgram and Plot	It is possible to evaluate Biacore 1 series runs with ***Inject and elute*** in the Biacore Insight Evaluation software. The ***Inject and elute*** command is supported in ***Sensorgram and Plot*** items. The same evaluation support is also available for Biacore T200 runs with ***Inject and recover*** commands.
Sample import	Automatic column mapping upon sample import has been introduced. The software tries to automatically map columns in the source material to corresponding variables in the method, based on the contents of the header row.
Plate layout	Possibility to export plate layout information from immobilization and analysis methods as text files, to enable direct import into liquid handlers. The export contains information about positions, solutions, volumes and other relevant sample variables.
Positioning	Improved error handling for positioning errors. The software is now more specific about what the problem is and which solutions that caused the issue.
Biacore Intelligent Analysis	New generalized affinity model for ***Biacore Intelligent Analysis*** that can handle any data that reaches steady state, not just data from fast dissociating binders. Additionally, ***Biacore Intelligent Analysis*** automatically selects the appropriate ***Affinity range position***, from which to extract the sensorgram response for fitting.
Biacore Intelligent Analysis	Possibility to edit classification names and classification purposes for newly created models. This enables greater flexibility in using Biacore Intelligent Analysis.

Software area	Description
Biacore Intelligent Analysis	Binding level screen supports predicition of super stoichiometry also when positive controls are not included in the run.
API	Support for automatic export of run data and evaluated data via an Application Programming Interface (API). Biacore Insight API is accessible with the Biacore Insight Data Integration Extension.
Plot	When hoovering over a point in the plot chart, the y-axis value is now displayed in the tooltip.
Epitope binning	Self-self subtraction has been introduced in the Epitope binning item. Sensorgrams that have the same first and second antibody can be subtracted from sensorgrams that have that antibody as the first antibody. This facilitates ranking of second antibody bindings.
Sensorgram and Kinetics/ Affinity	An Undo function has been implemented for Remove ranges in Kinetics/Affinity and Sensorgram items. When clicking the Undo button, the parts of the sensorgrams that were last removed are now included again. Undo is logged in audit trail for items created with a regulated procedure.
Kinetics/ Affinity	New columns for fit mode (global/local/constant) and initial value for each parameter can be added to the Result table in the Kinetics/ Affinity item. The new columns are included when exporting to Excel, pdf, ppt or via the API. Please note that the fit mode and initial values columns are not displayed in the table by default.
Evaluation software	Performance improvements have been implemented in the Biacore Insight Evaluation Software, mainly when evaluating affinity data, opening large evaluations and handling curve markers and curves with removed data ranges.
Evaluation software	It is possible to include the name of the run as a table column in all evaluation items.
Control software	The allowed length of solution names has been updated and harmonized in ***Method builder***, ***Immobilization and Interactive run***. Solution names with up to 50 characters are accepted.
Published procedures	Increased flexibility in flow cell selection for published procedures in Biacore 1 series. For example, if the procedure developer creates a method for flow cell pair (1, 2) and keeps the flow cell selection unlocked, then flow cell pairs (1, 2), (3, 4) and (5, 6) can be selected when running the procedure.

3 Resolved issues

The table below describes issues that have been resolved in Biacore Insight Software version 6.0.

Software area	Description
Immobilization	If an ***Aim for target*** level immobilization failed because the test injection was too slow, the surface wash with NaOH was not executed before the cycle was aborted. Electrostatically bound ligand might remain on the surface and potentially interfere with the next immobilization attempt. In version 5.0, the ***Test injection*** and ***Surface wash*** were two separate commands. In version 6.0 they have been combined into one. The wash is always performed, also when the test injection fails. (Ref. 5069)
Immobilization	Command names were not kept upon copy of a step in a custom immobilization method. The same issue occurred when a custom method was saved and re-opened. (Ref. 5129)
Immobilization	Upon restore of an immobilization run after loss of database connection, the chip information was not updated directly. It was updated when the next run started. (Ref. 5128)
Immobilization	It was possible to set up a Biacore 8 series ***Aim for immobilization*** method in fc 1 only and send it to the activity queue, although it is not possible to perform such a run. (Ref. 5125)
Immobilization	When enabling Injection markers during an Aim for immobilization run, a cascade of error messages was displayed. (Ref. 5086)
Import of sample information	Initial zeros in Sample IDs were removed when the sample information was imported. (Ref. 5097)

Software area	Description
Import of sample information	Cycle order was changed upon import of positions with pooling so that cycles with pooled positions were always run directly after each other. (Ref. 5084)
Positioning	When setting the Mix fraction as variable, the software displayed an incorrect volume for the mixing solution in Variables and positioning and Plate layout. The same volume was presented regardless of contact time and mix fraction. This defect occurred when typing, pasting or importing the mix fraction to the sample table. (Ref. 5188 and Ref. 5355)
Positioning	For Biacore 8 series methods using Mix, the software sometimes displayed a slightly too low volume for the solution and/or the mixing solution in Variables and positioning and Plate layout. The issue occurred when plates started to get full and positions had to be moved automatically by the positioning algorithm, i.e. when they could not get their preferred positions according to Positioning settings. The issue did not occur when moving positions manually via drag and drop. (Ref. 5355)
Method builder	For Biacore 8 series methods, sample identities in recurrent steps (repeated within another step) were lost when the method's channel usage was changed. When including channels that were previously unused, the name of the buffer was still displayed, instead of the correct solution. (Ref. 5145)
Database search	When scrolling the list of search results in the database view, the header row disappeared. (Ref. 4564)
Database search	When the search result was sorted by Type, items were not listed in alphabetical order. (Ref. 4563)

Software area	Description
Database restore	The following information was lost when restoring a run after losing connection to the database: • Concentration unit. • Dilution factor. • If parameters were locked for editing in the variable table in GxP mode. • If an injection had been paused/resumed/stopped. (Ref. 5123)
Action history	After updating the software to Biacore Insight Software version 5.0, the ***User*** column for existing entries in ***Action History*** was displaying the user that performed the upgrade of the database instead of the user performing the original action. (Ref. 5353)
Action history	When a procedure was opened from ***Action history*** (by double clicking a row or using the ***Actions*** menu) an exception often occurred, and the software was closed. (Ref. 5329)
Run	During an ongoing run, new events in the Cycle event log were not visible unless the view was manually scrolled to the bottom. (Ref. 4573)
Run	During long runs at 40 Hz, the instrument could experience USB communication issues and disconnect. (Ref. 5164)
Variable table	Single cycle kinetics concentration values were locked for editing in the evaluation variable table. (Ref. 4952)
Plot	Incorrect blank subtraction in the plot item's sensorgram panel if blanks had the ***Solvent. corr. out of range*** curve marker. (Ref. 5139)

Software area	Description
Concentration	Replicate calibration curves that were run in consecutive cycles, without samples in between, were not averaged correctly when using Calibration trends. (Ref. 5102)
Export of results	The concentration legend for single cycle kinetics was missing in exports. (Ref. 5156)
Kinetics/ Affinity	If the run name and/or ligand name was long, all intended information was not visible in the thumbnails. (Ref. 4979)

4 Known issues and limitations

The table below describes known issues and limitations in Biacore Insight Software version 6.0.

Software area	Description	Workaround
Immobilization	In the pre-defined immobilization method ***Immobilization low levels***, EDC and NHS are mixed in with ratio 20:80 to achieve the low levels of immobilization. If another Amine step is added via the ***Add step*** button, the mix ratio is set to standard 50:50 mix. (Ref. 5034)	Copy the existing step instead of adding a new step via the ***Add step*** button. Then the 20:80 ratio is preserved. Alternatively, the mix ratio can be modified in custom mode.
Immobilization	In the pre-defined immobilization method ***Immobilization low levels***, EDC and NHS are mixed in with ratio 20:80. But if the Immobilization procedure is changed from ***Specify contact time*** to ***Aim for target level***, the mix ratio is reset to standard 50:50 mix. (Ref. 5035)	The mix ratio can be modified in custom mode.

Software area	Description	Workaround
Immobilization	In some cases, especially when there are many different solutions in each step, repositioning via drag and drop can cause other existing positions to become scrambled in an unintuitive way. This applies to Biacore 1 series methods. (Ref. 5037)	Open the Positioning settings panel and un-check the check-box ***Autopopulate position upon manual reposition*** to get existing positions to stay in place.
Method builder	Positive numbers in scientific format (e.g. 1E4) that are entered in ***Variables and positioning*** are not kept when proceeding to ***Cycle overview*** or ***Plate layout***. They are automatically translated to general number format (10000). (Ref. 4965)	
Import	It is not possible to import values for the post-analyte contact time for ABA commands. Values appear correctly in the ***Import*** workspace but are replaced with zeros upon import. (Ref. 5357)	Type or paste the values directly into the sample table.
Positioning	It is not possible to select multiple positions in the microplate representation by using Ctrl+Click. (Ref. 5339)	Drag a rectangle around the positions that shall be selected.
Positioning	In some situations, turning off pooling does not have an immediate effect on the positioning. (Ref. 5120)	Click the ***Reset positions*** button in Positioning settings.
Kinetics/ Affinity	When performing an affinity fit to only 3 data points, the ***Chi2*** value is always reported as 0.0, regardless of the quality of the fit. It should be N/A since ***Chi2*** cannot be calculated when the number of data points equals the number of parameters. (Ref. 5119)	

Software area	Description	Workaround
Local database installation	If the local database installation fails, this is not indicated to the user or noted in the log files. (Ref. 5294)	
GxP	There is no GxP support for imported runs or evaluations, neither from Biacore T200 systems nor from Biacore 1 series or Biacore 8 series systems.	
Evaluation software	There is no restriction on the number of runs that can be selected and opened for co-evaluation. However, evaluation software performance will be slow when handling too large data sets.	
Export of results	Text may overlap in exports, for example when solution names, file and folder names are very long and do not contain spaces. There is no support for hyphenation of words.	Include spaces in long names.
Export of results	The software does not support special characters that do not exist in standard western fonts, such as smileys or non-Latin characters. When such characters are used in the software they may be ignored or shown as empty squares. Problems are known to occur in PDF exports and database exports but can also occur in other situations.	Do not use special characters in any text entered in the software.
Export of results	The affinity lines in On-off rate charts are not supported in exports to presentation due to limitations in Microsoft PowerPoint.	

Page intentionally left blank

cytiva

cytiva.com

For local office contact information, visit cytiva.com/contact

29798349 AA V:5 10/2024