

Biacore T200

GxP Handbook



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1 Introduction

Biacore™ T200 GxP Package adds support for GxP¹-regulated work to Biacore T200 Control Software and Evaluation Software. The software functionality is complemented by system qualification services that provide the necessary documentation for use of Biacore T200 in GxP regulated environments. This handbook describes the implementation of GxP support in the Control Software and Evaluation Software, and offers some guidance in establishing validated assays that use Biacore T200.

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¹ GxP: Collective abbreviation for GLP (Good Laboratory Practice), GCP (Good Clinical Practice) and GMP (Good Manufacturing Practice).

1.1 Important user information

Disclaimer

Cytiva provides system qualification services and software support for aspects of regulatory requirements for validated assays. Responsibility for developing and validating assay procedures lies however entirely with the user. Cytiva cannot be held responsible for failure to conform to validation requirements.

Important

To achieve full support for GxP compliance it is essential that security restrictions are implemented in the Microsoft® Windows® operating system as described in [Appendix A System administration, on page 54](#). Recommendations for configuring the Windows operating system for GxP compliance are given in a separate document.

1.2 Scope of GxP compliance

Regulatory authorities impose increasing demands on pharmaceutical development and manufacturing companies to use quality assured equipment and to follow detailed and carefully documented analytical and manufacturing procedures. The purpose of this control effort is to ensure consistent and reliable quality in pharmaceutical products that reach the market, and the prime mover is the United States Food and Drug Administration (FDA). Corresponding regulations in countries outside the United States often follow the lead of the FDA.

Quality assurance of equipment ("equipment qualification") aims to ensure that analytical and manufacturing instrumentation performs reliably according to the specifications of the manufacturer. Biacore T200 GxP Package offers qualification services in connection with installation and service maintenance of Biacore T200, to provide the user with the necessary documentation for equipment qualification.

The FDA rule commonly referred to as 21 CFR Part 11² provides regulations for electronic documentation of computer-based analytical and manufacturing procedures, and aims at ensuring that electronic records are complete and inviolate. Biacore T200 GxP Package provides support for compliance with 21 CFR Part 11 regulations with respect to electronic records. Electronic signatures are not supported in the current version of the product.

² Code of Federal Regulations (21 CFR Part 11) Electronic Records; Electronic Signatures (US Food and Drug Administration).

1.3 Additional documentation

This Biacore T200 GxP Handbook only covers aspects of Biacore T200 system and software that are directly relevant to GxP compliance. Use of the system and software is covered in full in separate handbooks:

- Biacore T200 Operating Instructions provides instructions for installing, operating and maintaining the Biacore T200 system in a safe way. All users must read the entire Operating Instructions before using the system.
- Biacore T200 Instrument Handbook covers operation and maintenance of the Biacore T200 instrument.
- Biacore T200 Software Handbook covers the use of the Control Software and Evaluation Software.
- Biacore T200 Immunogenicity Handbook describes the use of specialized functions for immunogenicity studies.

Understanding of these handbooks is essential to the correct operation of the system, and availability of the handbooks in the location where the system is used is normally a requirement for GxP work. The handbooks may be downloaded in PDF format) from [cytiva.com/biacore](https://www.cytiva.com/biacore).

2 GxP compliance

This chapter describes how Biacore T200 GxP Package implements support for GxP in the Control and Evaluation Software.

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2.1 User authorization levels

Access rights in Biacore T200 GxP software are controlled through membership of Windows users in the user groups **BIAadministrator**, **BIAdeveloper** and **BIAuser**, which are added to the Windows users and groups structure when the software is installed. In this way, logging in to Windows automatically identifies the access level of the user. Use of Biacore T200 software does not require a separate log-in. Windows users who are not members of any of the Biacore groups are not permitted to start Biacore T200 software. Users are assigned to the Biacore groups by the Windows administrator (see [Appendix A System administration, on page 54](#)).

Within Biacore T200 software, the groups are permitted access as follows. These restrictions should be complemented by Windows access control restrictions as described in [Appendix A System administration, on page 54](#).

BIAadministrator

Full access to system operation and evaluation. Certain settings in the software are only accessible to BIAadministrators, who therefore have the responsibility of determining these settings for all other users (see [Section 3.2 Software Preferences, on page 23](#)).

BIAdeveloper

Access to all functions in system operation and evaluation with the exception of software preferences. BIAdevelopers are responsible for developing and publishing procedures for routine use (see [Section 3.3 Developing procedures for publication, on page 29](#) and [Section 3.4 Publishing procedures, on page 30](#)).

BIAuser

Access only to published procedures for system operation and data evaluation, and to Control Software functions required for operation and maintenance of the instrument. BIAusers may not create or edit methods or wizard templates, and may only perform runs based on published procedures (see [Section 3.5 Performing runs, on page 42](#)). In the Evaluation Software, BIAusers may only work with one result file at a time, and may only open result and evaluation files derived from published procedures. BIAusers may only create new sensorgram, QC-plot and bar chart items. BIAusers may not create, import or edit evaluation models for kinetics, affinity and concentration determination.

Different access restrictions for the user groups provides a means for securing a robust GxP environment, where opportunities for departure from prescribed procedures are minimized. The highest robustness is achieved with operation of published procedures by BIAusers, who are not permitted to run any other type of analysis. Sufficiently restrictive Standard Operating Procedures (SOPs, [Section 4.3 Standard Operating Procedures \(SOPs\), on page 51](#)) can however achieve compliance for operation by BIAdevelopers and even BIAadministrators if required. Full support for file integrity and electronic records is provided for all user groups (see [Section 2.3 Data integrity, on page 11](#)).

2.2 Published procedures

Biacore T200 methods and wizard templates are prepared for GxP use by an operation referred to as publication which locks settings in the method or wizard and prevents changes from being made when the published procedure is run. Sample information can be entered at run time so that the same published procedure can be used to run different sets of samples (see [Section 3.3 Developing procedures for publication, on page 29](#)). A published procedure may also include an evaluation method that applies specified evaluation operations automatically to the results. For files derived from published procedures, BIAUsers may create sensorgram, QC-plot, and bar chart items in the Evaluation Software and may work with items created by any evaluation method included in the procedure, but may not create new items of any other kind. Any changes that are made to items in the evaluation are logged in an audit trail. Inclusion of an evaluation method in the published procedure thus ensures that critical evaluation steps are not bypassed, and is strongly recommended for all procedures intended for routine application.

Procedures are developed and published by users with BIAdeveloper (or BIAadministrator) status. Once published, however, the procedure settings cannot be changed at run time regardless of the authorization level of the user. Alteration of a published procedure requires publication of a new version, which automatically inactivates the previous version as soon as the new version becomes effective. Only the latest published version of a procedure can be used to perform a run. Publication keeps a full record of the version history, and includes an optional effective date setting whereby procedures can be set to become effective on a preset date in the future.

Note: *Kinetics summary operations are not subject to GxP compliance and cannot be included in published procedures.*

2.3 Data integrity

Data integrity is maintained in Biacore T200 GxP Package through file access control and enforced version handling. Automatic backup facilities are provided as an additional safeguard against data loss.

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2.3.1 File and folder security

Limiting access to secure folders and files ensures that electronic records of critical assays are complete and unmodified. Access control in Biacore T200 GxP Package is implemented through the Windows access control system with additional restrictions defined in the Biacore Control Software.

A secure folder structure for controlled file access and access control settings for users should be established by the system administrator. Further details and recommendations are given in [Appendix A System administration, on page 54](#).

Preferences in Biacore T200 Control Software determine the folders for published procedures and results. These settings can only be changed by the BIAadministrator (see [Section 3.2 Software Preferences, on page 23](#)). Procedures may only be run from the specified folder and results and evaluation files may only be saved in the specified folders (or in sub-folders under the respective specified folders). Result and evaluation files cannot be overwritten: edited versions must be saved as new files. With appropriate access control restrictions in the operating system, this provides maximum security for critical files.

2.3.2 File integrity

File name extensions

File name extensions for methods, wizard templates, procedures, results and evaluation methods are enforced in order to ensure correct identification of files in the operating system:

Table 2.1:

Methods	.method
Wizard templates	.bw<wizard identifier>
Procedures	.bpp
Results	.blr
Evaluation files	.bme
Evaluation methods	.evalmethod
Kinetics summary	.bks

Note: *These file types are registered in Windows. Depending on the Windows Explorer settings, the file extensions may be hidden in Explorer and in dialog boxes.*

Procedure files

Files for published procedures contain the version history of the procedure as well as a full copy of control method or wizard template and the evaluation method on which the procedure is based, so that deleting or changing the original method or template does not affect the procedure definition. Procedure files are safeguarded by a check-sum that renders files unusable if they have been modified by any means outside Biacore T200 Software.

Result file creation

Result files are created at the start of a run but are not finalized until a run is complete. If a file for an on-going run is opened in another instance of the Control Software (either on the same computer or on a different computer on a network), the additional instance opens a snapshot of the file without affecting the original file. The snapshot cannot be saved as a separate result file.

Result files contain the audit trail for the results as well as a full copy of the method or wizard template that produced the results and any method used for evaluation, so that the operational procedure can be recovered even if the original method or template files are deleted or changed.

2 GxP compliance

2.3 Data integrity

2.3.2 File integrity

Evaluation files

Evaluation files derived from published procedures include an audit trail that logs all changes made to the data in the results (such as exclusion of outliers or modification of the keyword table). If the keyword table is edited, any evaluation method in the published procedure will be re-applied as far as possible.

2.3.3 Back-up protection

Back-up functionality may be configured by the BIAadministrator using the **Tools** → **Preferences** command in the Control and Evaluation Software. When this function is turned on, saving a result or evaluation file automatically saves an additional copy to the specified back-up location. Automatically exported data is also copied to the backup folder.

The back-up location should be on a separate disk from the location used for results and evaluation, to provide added security against physical data loss.

2.3.4 Audit trails

A complete version history is maintained for published procedures, covering user identity, date and time of publication, status and comment for publication. The version history is stored as an integral part of the procedure file.

Result files and evaluation files derived from published procedures are annotated with an audit trail recording all changes made to the file contents. The user may enter a comment describing each change, and must acknowledge that all changes are approved before the changed file is saved.

The user identity and date/time stamp are included automatically. The audit trail is stored as an integral part of the result or evaluation file.

Result and evaluation files cannot be overwritten from within Biacore T200 software, and the recommended access control restrictions in the operating system protect files against deletion. The version history and audit trail saved with each file is thus supported by a full record of all previous versions of the file.

2.3.5 Electronic signatures

Electronic signatures are not supported in the current version of Biacore T200 GxP Package.

3 Operation

This chapter describes the GxP-specific aspects of Biacore T200 Control and Evaluation Software from the perspective of the three user levels (BIAadministrator, BIAdeveloper and BIAuser). The information provided here only covers differences in usage between GxP and non-GxP installations. For a description of how to use the Control and Evaluation Software, see the *Biacore T200 Software Handbook*.

A summary of the menu options available at the different user levels is provided in [Appendix B Software menu options, on page 61](#).

The table below summarizes the functions described in this chapter and the access level required for their use:

Table 3.1:

	BIAadministrator	BIAdeveloper	BIAuser	Section
Set preferences	Allowed	Denied	Denied	3.2
Publish procedures	Allowed	Allowed	Denied	3.4
Manual run	Allowed	Allowed	Denied	3.5
Wizard run	Allowed	Allowed	Denied	3.5
Method run	Allowed	Allowed	Denied	3.5
Procedure run	Allowed	Allowed	Allowed	3.5
Open files	Allowed	Allowed	Restricted	3.6
Evaluate data	Allowed	Allowed	Restricted	3.7
Create evaluation methods	Allowed	Allowed	Denied	3.3
Create and edit models for kinetics, affinity and concentration	Allowed	Allowed	Denied	-

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3.1 General features

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3.1.1 File integrity

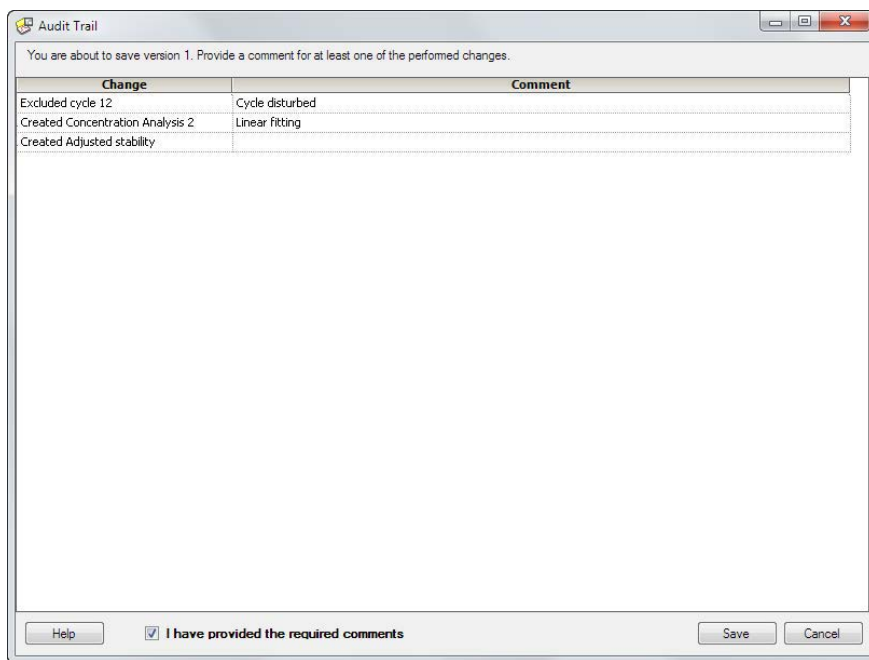
For both results and evaluation, files may not be saved with the same name as an existing file in the same folder. Edited results and evaluations must be saved as new files: a file name based on the original file name with an appended version number (incremented for each new version) is suggested by default. Use of the suggested file name is strongly recommended as an aid in tracking file versions.

If the BIAadministrator has forced save operations in a specified folder (see [Section 3.2 Software Preferences, on page 23](#)), the corresponding files must be saved in this folder (or in a folder structure within this folder), regardless of the authorization level of the user or the type of run being performed.

3.1.2 Audit trail

Changes made to the contents of result and evaluation files derived from published procedures are logged in the audit trail. For result files, this includes changes to the notebook and report point table but not changes to display settings. For evaluation files, all additions of and modifications to evaluation items are logged, as well as creation of custom report points and changes to the keyword table. The audit trail is automatically stamped with the user identity and date and time when the file is saved.

Comments must be entered for at least one of the changes. Whenever a new version of a result or evaluation file is saved, the user (regardless of user authorization level) must acknowledge that all required comments have been provided in the audit trail before the file can be saved.



Change	Comment
Excluded cycle 12	Cycle disturbed
Created Concentration Analysis 2	Linear fitting
Created Adjusted stability	

Help ☒ I have provided the required comments Save Cancel

Audit trails are saved only for files derived from published procedures.

3.2 Software Preferences

Preferences, accessed through the **Tools** → **Preferences** command, may only be set by the BIAAdministrator. The settings under **Preferences** apply to all users, regardless of authorization level. The GxP-related preferences described below are set independently in the Control and Evaluation Software.

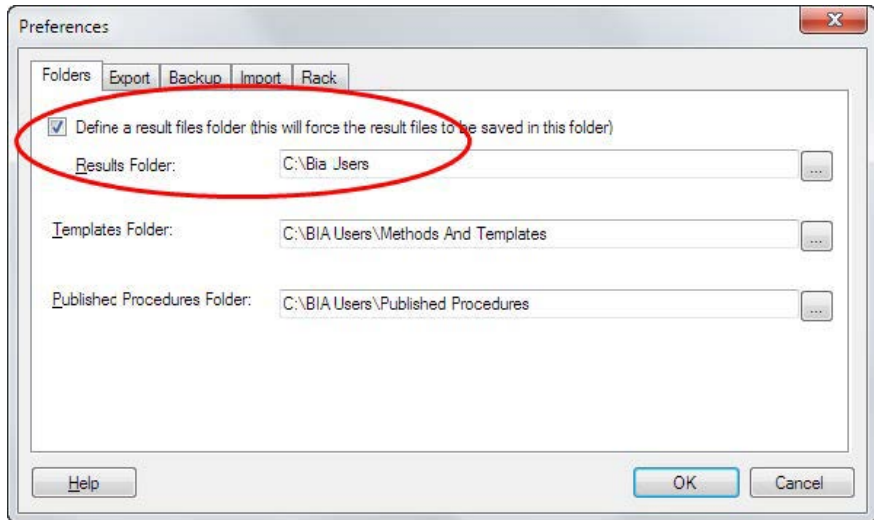
Note: The **Templates** folder specified on the **Folders** tab for preferences (see below) in the Control Software is enforced in GxP installations. Methods and templates cannot be saved outside this folder. In non-GxP installations the **Templates** folder provides a default location, but methods and templates can be saved outside the folder if desired.

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3.2.1 Result and evaluation files folders

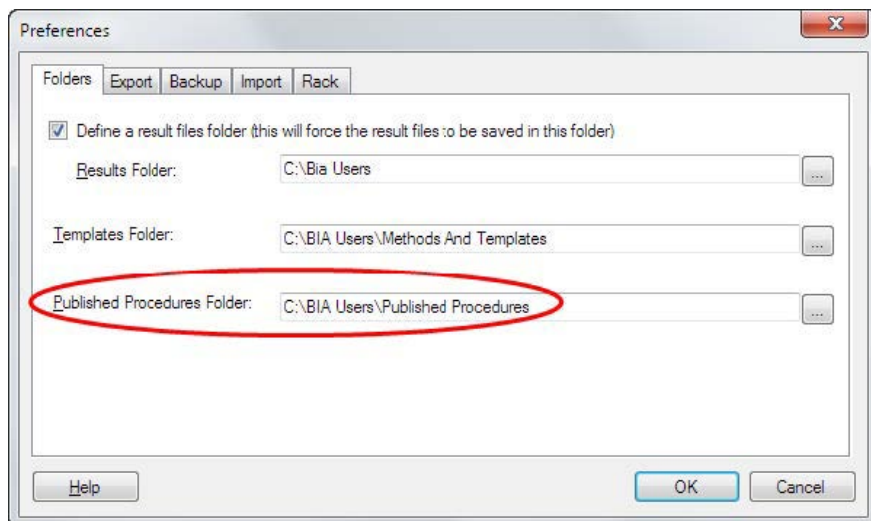
Check **Define a result files folder** in the preferences for the Control Software and **Define an evaluation files folder** in the preferences for the Evaluation Software to force result and evaluation files respectively to be saved in a specified folder or in a sub-folder under that folder. If this option is not checked, the files can be saved in any location.



In general, you should force result and evaluation files to be saved in a specified folder so that Windows access restrictions can be used together with Biacore T200 functionality for maximum protection of your files.

3.2.2 Published procedures folder

The root folder for storing published procedures is defined on the **Folders** tab.

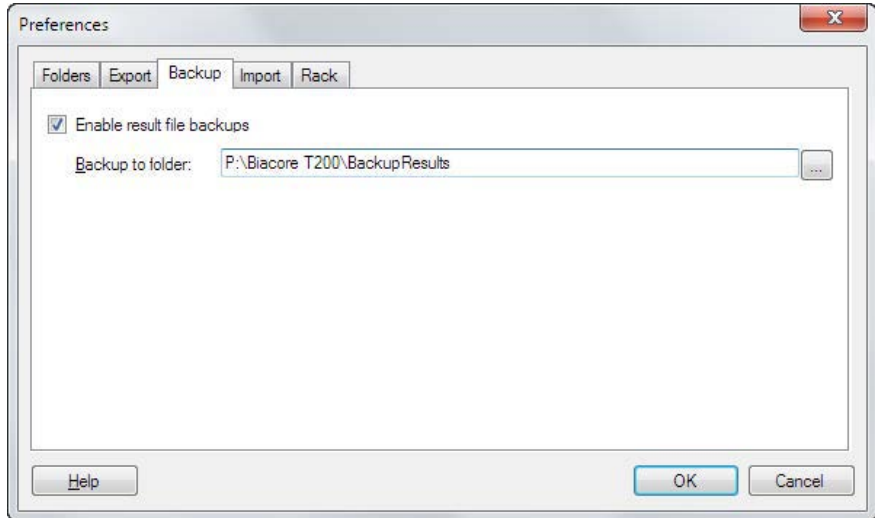


Procedure definitions may only be saved in this folder structure. The folder specification cannot be left blank. The folder should be subject to appropriate Windows access control restrictions (see [Appendix A System administration, on page 54](#)).

You should set the same folder in both Control and Evaluation Software. If the settings are different, procedures defined in the Control Software will not be accessible from the Evaluation Software and *vice versa*.

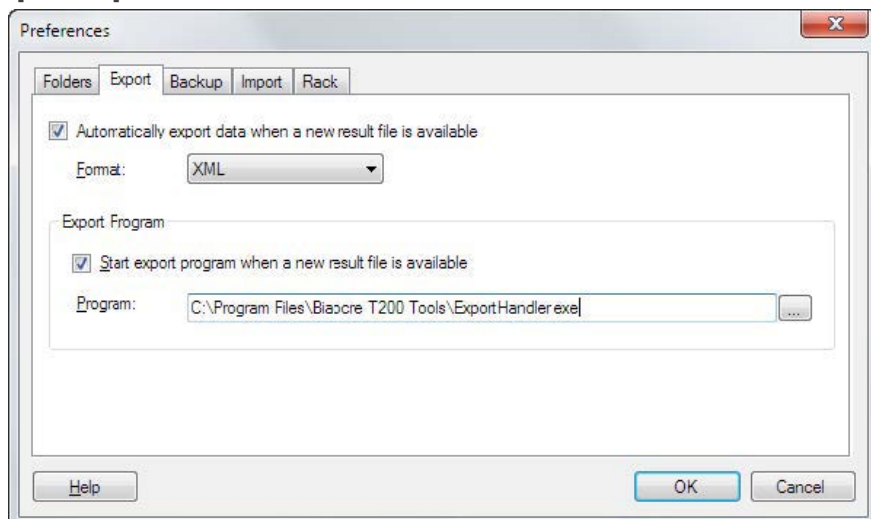
3.2.3 Backup options

A backup copy of result and evaluation files may be saved in a separate location if required. This option is set on the **Backup** tab in **Tools → Preferences**.



The settings for backup folders are independent in the Control and Evaluation Software.

3.2.4 Export options



Note: The export program example in this illustration is fictitious and is not part of the Biacore T200 software installation.

Biacore T200 GxP Package provides support for automatic export of data from result and evaluation files in XML or Microsoft Excel® format. Check **Automatically export data...** to activate this function: a file containing data from the result or evaluation file will be created with the same name as the file whenever a new version of the file is saved, using file name extension **.xml** or **.xls** for XML and Excel formats respectively. Export formats are described in the *Biacore T200 Software Handbook*.

The settings can also define a post-processing program that will start as soon as a new file becomes available. This program is invoked with the paths to the export file and the result or evaluation file as command line parameters. The program may typically be used to post-process the file and/or transfer the result or evaluation file (as a binary object) to a laboratory information management system (LIMS). Check **Start export program...** and enter a program name to use this function. Design and construction of a post-processing program is the responsibility of the system administrator. If you want to automatically export to Excel format you should specify Microsoft Excel or a compatible spreadsheet program as the export program.

3 Operation

3.2 Software Preferences

3.2.5 Import and Rack options

3.2.5 Import and Rack options

Preferences for **Import** and **Rack** apply also to non-GxP installations, and are described in the *Biacore T200 Software Handbook*.

3.3 Developing procedures for publication

Procedures are normally developed for publication by BIA developers, although BIA administrators are also authorized to publish procedures. Developing a procedure entails the following steps:

- Establish conditions for the assay and create a wizard template or method for the conditions. Make sure the template or method is completely defined, since only the detection mode and the sample table can be changed when the assay is run as a published procedure. Assay development and validation work should be done at this stage, before publishing the assay.
- Create an evaluation method if required for the assay that sets up all the required evaluation items. To create an evaluation method, create the evaluation items that you want to be included in the method and choose **File → Save Evaluation Method As**. If you want to test an evaluation method, open an appropriate result file and choose **File → Apply Evaluation Method** (see [Section 3.7 Evaluating data, on page 44](#)). If you export your results directly for evaluation in thirdparty software, you can skip the evaluation method.
- Publish a procedure containing the run method or wizard template and evaluation method as required.
- Write a Standard Operating Procedure (SOP) describing how the assay should be used (see [Section 4.3 Standard Operating Procedures \(SOPs\), on page 51](#)).

3.4 Publishing procedures

Procedures are published in order to provide defined and locked experimental conditions for GxP operation by BIAusers. Published procedures are based on saved methods or templates: the published procedure contains a copy of the method or template settings so that changes to the original method or template made after a procedure has been published do not affect the procedure.

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3.4.1 What can be published?

A published procedure contains one wizard template or method from the Control Software and usually one evaluation method from the Evaluation Software.

Wizard templates

Wizard templates for **Immobilization pH scouting**, **Assay development**, **Control experiments**, and **Thermodynamics** cannot be published. All other wizard templates can be published.

Methods

All methods can be published.

Evaluation methods

All evaluation methods can be published, but the scope of published evaluation methods is limited for some items (see [Section 3.4.2 Scope of published procedures, on page 32](#)).

A procedure may be published without an evaluation method, but results obtained from running such a procedure can only be evaluated by users with BIAadministrator or BIAdeveloper status (see [Section 3.7 Evaluating data, on page 44](#)) or in third-party software.

Note: *Evaluation in Biacore T200 software of runs derived from procedures that lack evaluation methods is not recorded in an audit trail and does not comply with strict GxP practices. Avoid publishing procedures without evaluation methods for use in controlled GxP environments.*

3.4.2 Scope of published procedures

The following components are published in a procedure:

Wizard templates

All wizard settings are published. At run time, the user may change the detection mode within limits imposed by the mode set in the template and may edit the sample table and rack positions. All other settings are locked.

Note: *In all assay wizard templates, at least one row must be entered in the sample table before the **System preparations** and following dialogs can be accessed. If you want to provide the user with an empty sample table in the published procedure, enter a dummy row in the wizard template and include instructions in the SOP to replace this row with the first sample at run time.*

Method Builder methods

Variable parameters that are defined in the method are locked in the published procedure. At run time, the user may change the detection mode within limits imposed by the mode set in the method and may edit the values of variables that are set to be defined at run-time.

Evaluation methods

All evaluation items created in the session, with the exception of **Thermodynamics** items and kinetic evaluations that use multiple $R_{\max}$, are saved in the evaluation method and will be created if possible when the method is applied to a result file. The following restrictions apply:

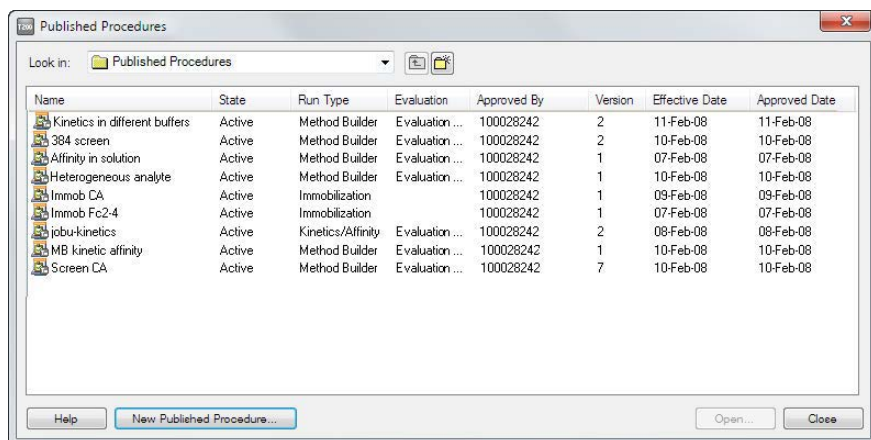
- Median filter settings in result plots are not saved.
- Standard sensorgrams in **Sensorgram Comparison** items are either saved in the evaluation method or taken from the data set to which the method is applied and identified by a naming prefix defined in the evaluation method (see the *Biacore T200 Software Handbook* for details). When the method is applied, the original files for standards saved in the method are not accessed. Sensorgrams run with assay step purpose **Control sample** are compared as controls. All other sensorgrams are compared as samples. The assignment to standards, controls and samples cannot be changed in the **Sensorgram Comparison** item once the method has been applied.
- For **Kinetics/Affinity** analysis items, only one $R_{\max}$ subset and the first fit in any one item will be saved in the method.
- Kinetic and affinity screening evaluations in evaluation methods are not completed automatically, and the user (including BIAusers) may change the selection of data series and the settings for evaluation.
- For **Affinity Screening** that uses constant $R_{\max}$, the $R_{\max}$ value is not saved in the evaluation method and must be entered when the method is applied.

3.4.3 Publishing a new procedure

To publish a new procedure, choose **File** → **Published Procedures** in either the Control or Evaluation Software and click on **New Published Procedure** in the dialog box.

Note: Procedures published with software version 3.2 or later include a timestamp (hh:mm) in the **Approved Date** column.

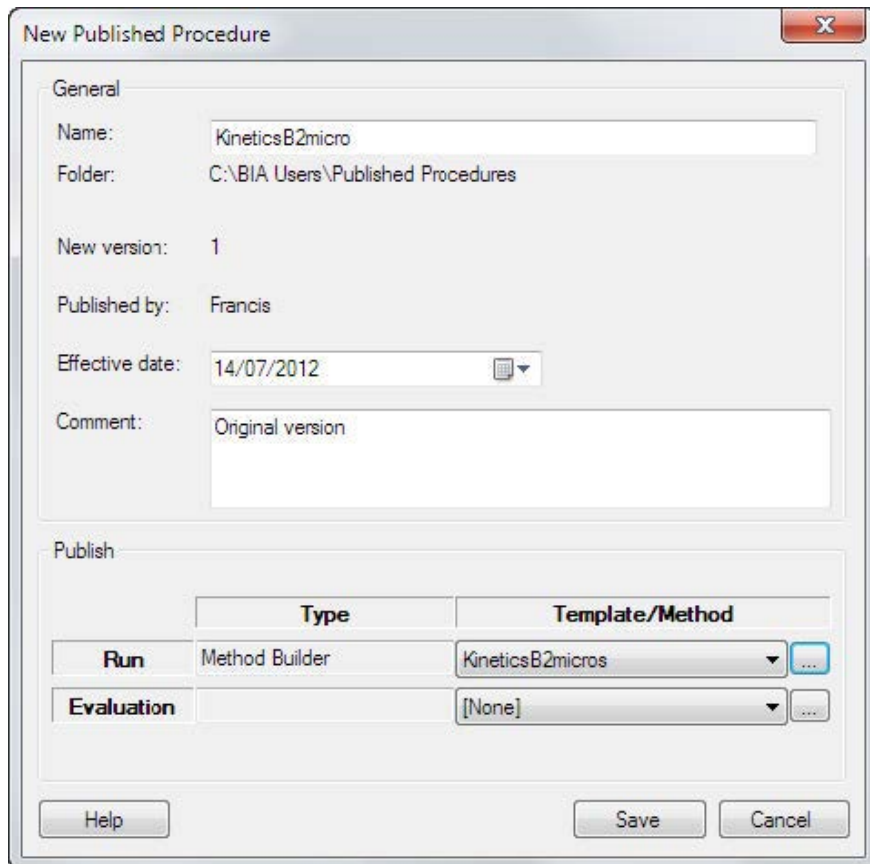
The menu options in the Control and Evaluation Software are entirely equivalent assuming that the folder for published procedures is the same in both programs. Publication facilities are provided in both programs for convenience.



3 Operation

3.4 Publishing procedures

3.4.3 Publishing a new procedure



New Published Procedure

General

Name: KineticsB2micro

Folder: C:\BIA Users\Published Procedures

New version: 1

Published by: Francis

Effective date: 14/07/2012

Comment: Original version

Publish

	Type	Template/Method
Run	Method Builder	KineticsB2micros
Evaluation		[None]

Buttons: Help, Save, Cancel

Enter a name for the procedure. The root folder where the procedure will be saved is set in **Preferences** and cannot be changed (see [Section 3.2.2 Published procedures folder, on page 25](#)).

Choose an **Effective date** if you want the procedure to be activated at a future date. Selecting an effective date in the future places the procedure "on hold" until the effective date occurs (according to the system clock on the local computer). The procedure will become available for use from time 00:00 on the effective date. The previous version (if any) will remain active until the effective date is reached. The default is today's date, so that the procedure is activated immediately. You cannot choose an effective date in the past.

A comment describing the published procedure is required.

Choose a method or template for the run and evaluation. Methods and templates can be taken from any location to which the user has access. The evaluation method is optional.

Note: *Make sure the run method or template is complete. Procedures that are published using an incomplete method or template cannot be run, since the missing settings are not accessible at run time.*

3 Operation

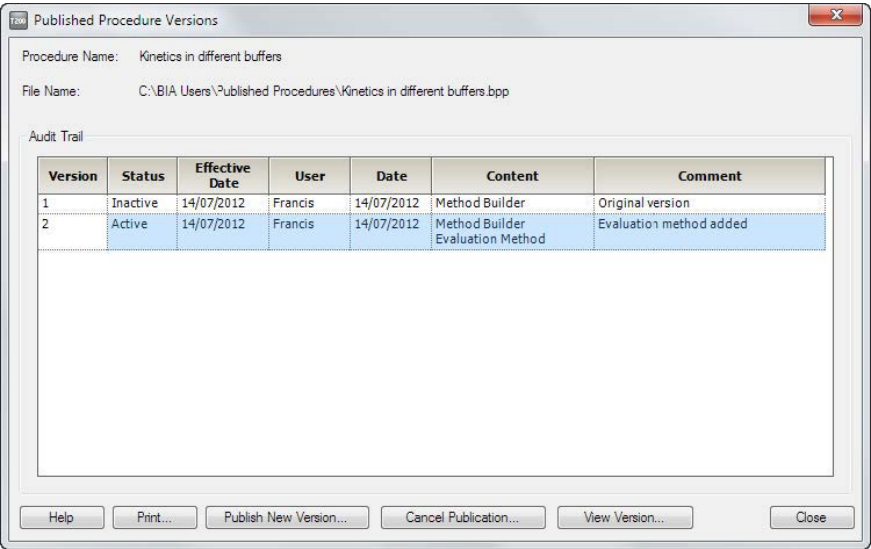
3.4 Publishing procedures

3.4.3 Publishing a new procedure

Make sure also that the evaluation method is matched with the run method or template. If the procedure is published with an unsuitable evaluation method, satisfactory evaluation of the results will not be possible.

3.4.4 Procedure versions and status

To view the version history and status of a published procedure, choose **File** → **Published Procedures**, select the procedure and click **Open**.



Note: Procedures published with software version 3.2 or later include a timestamp (hh:mm) in the **Date** column.

The status can be one of the following:

Table 3.2:

Active	This version is currently active and is available for use with the Run:Run Published Procedure command. Only one version can be active at any given time.
Inactive	The version has been active at some time but has been superseded by a later version or the procedure has been canceled (see Section 3.4.6 Cancelling a procedure, on page 40). Inactive versions cannot be used for procedure runs.
Canceled	The version has been canceled either by later publication of a version with an earlier effective date or because the procedure has been canceled (see Section 3.4.6 Cancelling a procedure, on page 40) before the version became active. Canceled versions cannot be used for procedure runs.
Approved	The version has been published with an effective date that has not yet been reached. The version is scheduled to become active on the effective date.

The dialog box may also contain a **Canceled** entry with no version number, effective date or type, indicating that the procedure has been explicitly canceled (see [Section 3.4.6 Cancelling a procedure, on page 40](#)).

Choose **Print** to print the version history as displayed on the screen.

Select a version and click **View Version** to display a summary of the version definition.

Published Procedure: Kinetics in different buffers Version: 2

Properties | Run Template/Method | Evaluation Method

Name: Kinetics in different buffers

Folder: C:\BIA Users\Published Procedures

New version: 2

Published by: Francis

Published date: 14/07/2012

Effective date: 14/07/2012

Comment: Evaluation method added

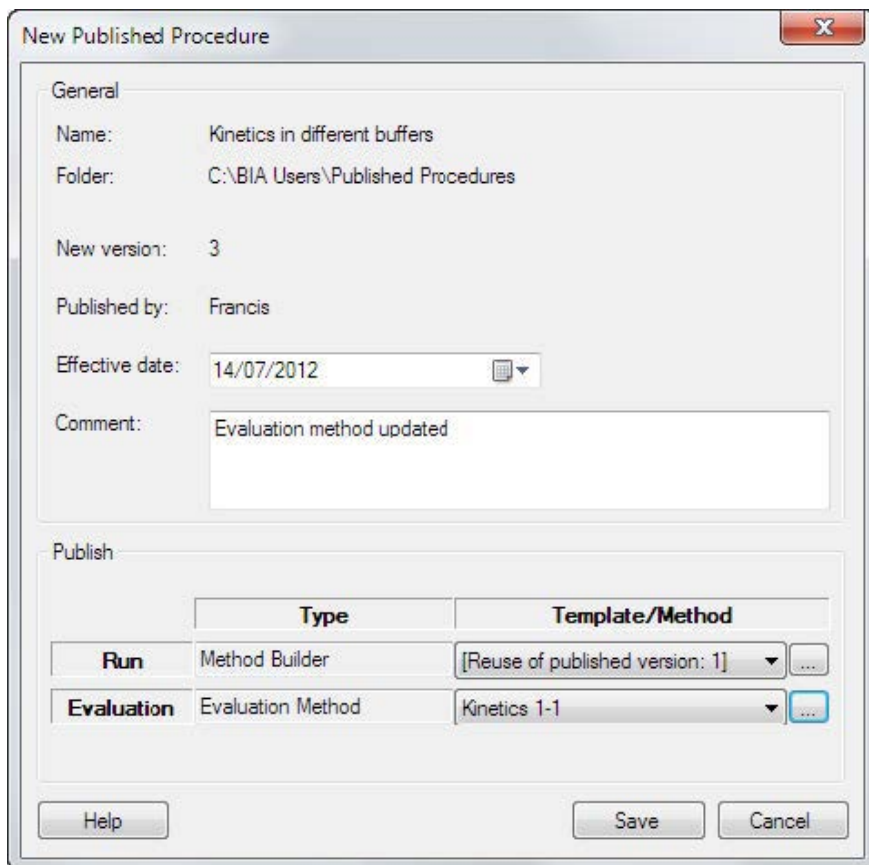
	Type
Run	Method Builder
Evaluation	Evaluation Method

Help Close

Summaries of the methods used in the published procedure are given on the **Run Template/Method** and **Evaluation Method** tabs.

3.4.5 Publishing a new procedure version

To publish a new version of an existing procedure, choose **File** → **Published Procedures**, select the procedure and click **Open**. In the **Procedure Versions** dialog box, click **Publish New Version**. Choose new methods or templates or select **[Reuse...]** to use a method or template from a previously published version. Enter a comment and set an effective date as described for publication of new procedures above ([Section 3.4.3 Publishing a new procedure, on page 33](#)).



New Published Procedure

General

Name: Kinetics in different buffers
 Folder: C:\BIA Users\Published Procedures
 New version: 3
 Published by: Francis
 Effective date: 14/07/2012
 Comment: Evaluation method updated

Publish

	Type	Template/Method
Run	Method Builder	[Reuse of published version: 1] ...
Evaluation	Evaluation Method	Kinetics 1-1 ...

Buttons: Help, Save, Cancel

Note: If you select **[Reuse...]**, the version of the method or template in the selected procedure will be used regardless of any changes that might have been made to the method or template file outside the procedure.

There are no restrictions on the choice of method or wizard template for publishing a new version of a procedure. A new version of a procedure does not necessarily have to be based on a revision of the original method or template.

If there are procedure versions published with an effective date that has not yet been reached, and another version is published with effect from an earlier date, all later versions will be canceled. Several versions can have the **Approved** status at the same time provided that the publication date follows the same chronological sequence as the effective date. Only one version may however be active.

When the procedure is saved in a second or later version, the **Procedure Versions** dialog box (see [Section 3.4.4 Procedure versions and status, on page 36](#)) is displayed automatically, allowing you to review the procedure publication status and to view and print the procedure definition.

3 Operation

3.4 Publishing procedures

3.4.6 Cancelling a procedure

3.4.6 Cancelling a procedure

To cancel a published procedure, select the procedure in the **Procedure Versions** dialog box and click **Cancel Publication**. The currently active and all approved versions of the procedure will be canceled, and the procedure will no longer be available for running. Cancellation takes effect immediately, and is recorded in the procedure version history as an entry without a version number.

Note: *Cancelling a procedure does not remove the procedure file from the published procedures folder. Cancellation is however not reversible, and a new version must be published before the procedure can be used.*

3.4.7 Extracting methods from a procedure

To extract the methods or templates from a published procedure, open the **View Versions** dialog box ([Section 3.4.4 Procedure versions and status, on page 36](#)) and click on **Extract** for the run or evaluation method.

3.5 Performing runs

Compliance in operation of Biacore T200 GxP Package is based on the guiding principle that all validated runs are performed from published procedures. All users may perform procedure-based runs with the **Run** → **Run Published Procedure** command. This is however the only run option available to BIAusers. BIAusers also have access to menu options which cover the operations necessary for performing runs (e.g. dock/undock the sensor chip) and for instrument maintenance in the **Tools** menu.

BIAadministrators and BIAdevelopers may run manual, method-based and wizard-based runs as described in the Biacore T200 Software Handbook. The results must however be saved within the specified folder tree if the BIAadministrator has set the Define a result files folder preference ([Section 3.2.1 Result and evaluation files folders, on page 24](#)). The menu options available to the different user levels are summarized in [Appendix B Software menu options, on page 61](#).

Note: *Depending on the method definition or wizard template on which a published procedure is based, there may be important aspects of the operational procedure that are not defined in the procedure (e.g. choice of flow cell). These should be carefully controlled through SOPs (see [Section 4.3 Standard Operating Procedures \(SOPs\), on page 51](#)).*

3.6 Opening files

BIAdministrators and BIADevelopers may open all types of files in the Control Software, including methods, wizard templates and result files. BIAUsers are only allowed to open result files (.blr) created from published procedures and from maintenance tools (e.g. **System Check**), and may not view the method or template included with result files.

The **File** → **Append Result File** option is not available for result files derived from published procedures.

The **File** → **Open** operation in the Evaluation Software permits only one file to be opened. BIAUsers may not append result files to the current evaluation session, and may consequently only work with one result file per session.

3.7 Evaluating data

In this section

Section		See page
3.7.1	BIAadministrators and BIAddevelopers	45
3.7.2	BIAusers	46

3.7.1 BIAadministrators and BIAdevelopers

BIAadministrators and BIAdevelopers can evaluate all files. For results derived from procedures that include an evaluation method, evaluation is performed automatically in accordance with the method. BIAadministrators and BIAdevelopers may then create new evaluation items and custom report points: all changes are logged in the audit trail for the evaluation. For files derived from procedures that do not include an evaluation method, the results may be evaluated freely and no operations are logged in the audit trail.

Existing evaluation methods can be applied to result files that are not derived from published procedures (or derived from published procedures that do not include an evaluation method) by selecting **File → Apply Evaluation Method**. Choose the method to apply. A summary of the method will be presented (and can be printed) before the method is applied. A different method can be chosen if desired using the **Browse** function in the method summary dialog.

3 Operation

3.7 Evaluating data

3.7.2 BIAusers

3.7.2 BIAusers

BIAusers may only open result files derived from published procedures that include an evaluation method, and any evaluation method in the procedure is applied automatically. The user may create new sensorgram, QC-plot, and bar chart items and may edit the keyword table and existing evaluation items, but may not create new evaluation items of any other type. All changes made by the user to the evaluation are logged in the audit trail.

BIAusers cannot open files derived from procedures that do not contain an evaluation method.

3.8 Changing users

In order to change users in a Biacore T200 system, it is necessary to log off from Windows so that a new user can log on. This entails shutting down all running programs. Shutting down Biacore T200 Control Software prompts the user to choose how the instrument should be left. If **Standby** mode is chosen, **Standby** will continue to run after the Control Software is shut down. This mode is recommended if the instrument is to be left for periods of up to 7 days.

If the computer is to be left unattended without logging off from Windows, the workstation should be locked by pressing **Ctrl-Alt-Delete** and choosing **Lock Workstation** or the equivalent from the available options. A passwordprotected screensaver may also be installed as an additional precaution against unauthorized access.

As a general recommendation, users should close Biacore software and log off from Windows when they leave the computer at the end of a work session. This will avoid the situation that a new user is forced to reboot the computer in order to log on if the user who locked the workstation (either by command or through a screensaver) is not available at the time.

4 GxP compliance in practice

This chapter offers some practical guidelines for working with Biacore T200 in GxP environments, and covers aspects of compliant work that are not directly regulated through the functionality of Biacore T200 GxP Package.

Compliance in operation of Biacore T200 GxP Package is based on the guiding principle that all validated runs are performed from published procedures. While compliance may in principle be established through strict SOPs for runs based on methods or application wizards, or even for manual runs, this approach makes unnecessarily heavy demands on construction and validation of SOPs and is not recommended.

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4.2	Assay development and validation	50
4.3	Standard Operating Procedures (SOPs)	51
4.4	Archiving requirements	53

4.1 Data storage discipline

Maintenance of electronic records is a critical aspect of 21 CFR Part 11 compliance, and Biacore T200 GxP Package safeguards the records of executable experimental procedures (as published procedures), raw data (as result files) and data evaluation (as evaluation files). These items are stored in protected folder structures and cannot be edited, deleted or overwritten from within the software. In addition audit trails are enforced for changes made to result files and for saved evaluation files.

Subfolders can be created within the protected folder structure and inherit the access control restrictions that apply to the protected root. Procedures can be accessed and results and evaluation files stored in subfolders under the respective folders specified in the preferences (see [Section 3.2 Software Preferences, on page 23](#)).

Methods and wizard templates can be created and edited by BIA administrators and BIA developers, and strict regulations for these file types are not enforced. These files are not needed in order to run published procedures, and are thus not critical for GxP work. However, discipline with respect to storage and handling of method and template files can help to maintain a total software environment that is more easily validated and audited. The following points may be borne in mind:

- Keep methods and wizard template files in well organized folder structures that can be related to the structures used for procedures, result files and evaluation.
- During assay development work, maintain a careful version history of methods and wizard templates. Save new versions as new files rather than overwriting existing files.
- Keep documented copies of the methods and wizard templates used in published procedures. For audit purposes, however, extract the method or template from the procedure definition ([Section 3.4.7 Extracting methods from a procedure, on page 41](#)). The copy stored in the procedure definition is guaranteed to be valid for runs performed with the procedure, whereas there is no guarantee other than individual discipline that the original method or template is unchanged.

4.2 Assay development and validation

A Biacore T200 assay can form part of a validated laboratory procedure, although the GxP support provided by Biacore T200 GxP Package is not in itself sufficient to ensure validation (see [Section 4.3 Standard Operating Procedures \(SOPs\), on page 51](#)).

Development of an assay for validation may involve a comprehensive series of pilot experiments, optimization and performance verification which form the basis for settings in the final published procedure (see for example the Biacore Concentration Analysis Handbook which provides guidance for validation parameters in Biacore-based concentration assays). Such experiments may be performed with manual, method-based or wizard-based runs.

Development is the responsibility of users with BIAdeveloper status: BIAusers are only authorized to run published procedures and do not therefore take part in development work. The results of assay development runs are subject to the same restrictions on saving as the results of assay runs, so that the GxP Package ensures electronic records for assay development as well as routine assays. In addition, copies of the methods or wizard templates used in assay development are always saved in the respective result files, so that a full version history of the development can be reconstructed if necessary.

Result files derived from manual runs do not contain any record of the operations performed (other than the event log from the run), and manual runs are therefore not generally recommended for assay development work. The choice between method- and wizard-based development should be made with a view to the intention in the final assay. Remember that wizard templates may be opened in Method Builder for further refinement, but methods may not be converted into wizard templates.

4.3 Standard Operating Procedures (SOPs)

SOPs that specify in full detail how an assay should be performed and documented are an essential feature of validated assays in a GxP environment. The use of published procedures in Biacore T200 contributes to the regulation of operating procedures, but cannot cover all aspects of GxP work. As a guiding principle, an SOP should give complete and unambiguous instructions for how an assay should be performed from start to finish, in such a way that a user with a minimum of prior knowledge can perform the assay correctly.

Preparation of SOPs for validated assays is the responsibility of the customer. Some aspects that should be considered are listed below. Where appropriate, instructions may be written in the **Prepare Run Protocol** for the run method or template, so that they are presented to the user at run-time.

- Include detailed instructions concerning preparation of buffers, reagents and samples. Calibration requirements for measuring equipment (e.g. balances, pipettes and pH meters) should be clearly stated and calibration procedures should be documented. Reagent specifications, including lot numbers where appropriate, should be documented for each assay.
- Preparation of the sensor surface for Biacore assays is an essential part of the assay procedure. The immobilization procedure may be published as a procedure in itself. Any other requirements for surface preparation should be included in the SOP, together with clear directives on the allowable time and conditions for storage of sensor chips between surface preparation and assay execution and whether sensor chips may be re-used between assays. Specify requirements for any conditioning and/or start-up cycles using dummy sample injections for conditioning the sensor surface and/or flow system.
- Depending on the performance demands for the assay, instrument preparation routines may be included in the SOP, for example cleaning and priming the flow system and allowing a minimum stabilization time in standby mode after docking the sensor chip.
- Certain features of the assay operation in Biacore T200 may not be covered by the settings in the published procedure (see [Section 3.3 Developing procedures for publication, on page 29](#)). Make sure the SOP includes clear instructions for docking the sensor chip, selecting the rack base and so on as appropriate.
- The SOP should specify in detail how to handle operations in the evaluation software that are not performed automatically by the method.
- The SOP may include instructions for where the results of an assay should be saved. The software restricts saving to within a protected folder structure, but including more detailed instructions in the SOP will help to reduce potential confusion in data storage and retrieval.
- The SOP should specify what data should be printed as hard copy for archiving.
- In order to ensure that the Biacore T200 system is maintained correctly, procedures to be followed on completion of an assay should be included in the SOP. The recommended procedure is to leave the instrument in standby mode with distilled water or buffer for up to 7 days, and to shut down the system for longer periods.

4 GxP compliance in practice

4.3 Standard Operating Procedures (SOPs)

- Regular cleaning and maintenance of the instrument is important for best performance, and should be specified in a separate SOP.

It is a general requirement that SOPs and user documentation are kept readily available for all users (preferably close to the system). Documentation for Biacore T200 GxP Package comprises:

- Biacore T200 Operating Instructions
- Biacore T200 Instrument Handbook
- Biacore T200 Software Handbook
- Biacore T200 GxP Handbook
- Biacore T200 Immunogenicity Handbook

4.4 Archiving requirements

The intention of electronic records for computer-controlled assay procedures is to document the assay and the results in as much detail as possible, so that the procedure can be repeated exactly in another laboratory and/or at a later date. For this purpose, it is important that the computer environment is archived as far as possible together with the assay results. Archiving the hardware environment is scarcely practicable (although hardware configuration may be crucial to the performance of the assay): it is however important to archive or at least document the software environment in order to be able to recreate the assay situation faithfully.

Details of the Biacore instrument type and serial number and software versions are recorded in the **File Properties** with each result file saved from Biacore T200. The version number of the operating system is shown in the **System** information in the Windows Control Panel or the **Computer** properties in Windows. Additional version information on Biacore and Microsoft components can be obtained with the Biacore Software Problem Report, accessed through **Tools** → **Service Tools** in the Control Software. This tool is designed to gather system information as an aid to Cytiva staff in identifying software problems.

Note: *The documentation provided by the Software Problem Report is not a complete list of all components in the software environment. Documentation through this tool should not be seen as an alternative to archiving the complete software environment in strictly regulated situations.*

For archiving printed material, make sure you use archival ink cartridges or toner in the printer.

Appendix A

System administration

This appendix describes how to install and manage Biacore T200 GxP Package software, and includes recommendations for user administration and data storage structures.

In this chapter

Section		See page
A.1	Software installation	55
A.2	User management	56
A.3	System access control	57
A.4	Data storage management	58

A.1 Software installation

The software is installed from the supplied CD. Installation requires a product key for Biacore T200 GxP Package.

In network environments, the software must be installed on all workstations where it will be used. A separate software license is required for each installation. Network installation of the software is not supported.

Installation of the software will add the Biacore groups **BIAadministrator**, **BIAdeveloper** and **BIAuser** to the Windows local users and groups. No members will be assigned to these groups by the installation procedure.

A.2 User management

In order to use the Biacore T200 software, Windows users must be granted membership in one of the three Biacore user groups. Windows users who are not members of any Biacore group are not permitted to run Biacore T200 Control or Evaluation Software when the Biacore T200 GxP Package is installed. The responsibilities of the groups are summarized in [Section 2.1 User authorization levels, on page 9](#).

Use the **Local Users and Groups** function in Windows computer management to create users and assign them to the Biacore groups. Creation of users and assignation to Biacore groups is the responsibility of the system (IT) administrator.

Note: *The three Biacore groups form a strict hierarchy of access rights, with BIAadministrator at the top of the hierarchy and BIAuser at the bottom. Windows users should not be assigned to more than one Biacore group.*

Use the **Local Security Policy** function in Windows administrative tools to set password and account lockout policies, file audit policies and security policies. Minimum length unique passwords with enforced password history are recommended for GxP installations. Audit of denied file operations can be activated to track attempted modification or removal of protected files.

A.3 System access control

As a general routine, users should be instructed to log off Windows whenever they finish using the system to prevent unauthorized access to the system through their user accounts. Logging off Windows closes all open programs. If the computer is to be left unattended without logging off from Windows, the workstation should be locked by pressing **Ctrl-Alt-Delete** and choosing **Lock Workstation** or equivalent from the available options. A password-protected screensaver may be installed to reinforce system security.

A.4 Data storage management

Conformance with 21 CFR Part 11 regulations requires careful control of the creation, modification and deletion of electronic records. In the context of Biacore T200 GxP Package, these records comprise published procedure files (which control routine assay operation), result files and data evaluation files. The software includes functions managed by BIAadministrators for controlling the location of these files (see [Section 3.2 Software Preferences, on page 23](#)). For full safeguard of electronic records, the software functions should be complemented with access control restrictions in Windows. Access control restrictions are also recommended for method and wizard template files even if these are not normally used for execution of validated assays, and also for the backup folder.

In this section

Section		See page
A.4.1	File and folder structure	59
A.4.2	File and folder security	60

A.4.1 File and folder structure

To facilitate organization of data storage, separate folders should be created for storage of files. Installation of Biacore T200 GxP Package creates the folder **Published Procedures** under **C:\BIA Users**. Additional folders for results and evaluation files should be created, for example under **C\BIA Users**; in addition, a back-up folder should be created on a separate physical unit if the automatic back-up function is used (see [Section 3.2.1 Result and evaluation files folders, on page 24](#)).

Detailed design of the data storage structure may be adapted to the needs of each installation, but the essential features of the suggestion here are as follows:

- All Biacore user files are collected under a single top-level folder, simplifying collective management operations.
- Each type of file (procedures, templates, etc) is collected under its own root folder. This simplifies access control management (see [Appendix A.4.2 File and folder security, on page 60](#)) since subfolders created under each root can be set to inherit the access control settings from the parent folder.
- Subfolders for each file type may be organized according to the demands of the installation, for example by user or by assay project.
- Backup files should be stored on a separate physical unit from results and procedures for data security reasons.

The BIAadministrator or IT administrator is typically responsible for creating and maintaining the data storage structure. Access control restrictions should be exploited to prevent other users from making changes to the file and folder structure.

A. System administration

A.4 Data storage management

A.4.2 File and folder security

A.4.2 File and folder security

File and folder security is most conveniently controlled at the Biacore group level. Basic recommendations for access control for BIAdevelopers and BIAusers may be obtained from Cytiva.

Appendix B

Software menu options

This Appendix lists the availability of menu options in the software for the three user access levels. Options marked as available may be grayed out in some contexts.

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B.2	Evaluation Software	64

B. Software menu options

B.1 Control Software

B.1 Control Software

Note: The **File** → **Audit Trail** option is only available for files derived from published procedures.

Table 5.1:

	BIAadministrator	BIAdeveloper	BIAuser
File			
Open/New Wizard Template	Yes	Yes	No
Open/New Method	Yes	Yes	No
Open	Yes	Yes	Yes (published only)
Close	Yes	Yes	Yes
Save	Yes (only during run)	Yes (only during run)	Yes (only during run)
Save As	Yes	Yes	Yes
Print	Yes	Yes	Yes
Audit Trail	Yes	Yes	Yes
Properties	Yes	Yes	Yes
Export	Yes	Yes	Yes
Published Procedures	Yes	Yes	No
Exit	Yes	Yes	Yes
Edit			
Report Points	Yes	Yes	Yes
View			
Chip Properties	Yes	Yes	Yes
Title	Yes	Yes	Yes
Scale	Yes	Yes	Yes
Adjust Scale	Yes	Yes	Yes
Unzoom	Yes	Yes	Yes
Reference Line	Yes	Yes	Yes
Baseline	Yes	Yes	Yes
Show Only Current Curve	Yes	Yes	Yes
Show Curves of Same Type	Yes	Yes	Yes
Show All Curves	Yes	Yes	Yes
Event Log	Yes	Yes	Yes
Method	Yes	Yes	No

B. Software menu options

B.1 ControlSoftware

Wizard Template	Yes	Yes	No
Notebook	Yes	Yes	Yes
Wizard Results	Yes	Yes	Yes
Sensorgram Markers	Yes	Yes	Yes
Run			
Manual Run	Yes	Yes	No
Wizard	Yes	Yes	No
Method	Yes	Yes	No
Published Procedure	Yes	Yes	Yes
Tools			
Prime	Yes	Yes	Yes
Shutdown	Yes	Yes	Yes
Biacore T200 Evaluation	Yes	Yes	Yes
Standby	Yes	Yes	Yes
Stop Standby	Yes	Yes	Yes
Eject Rack	Yes	Yes	Yes
Rack Illumination	Yes	Yes	Yes
Insert Chip	Yes	Yes	Yes
Eject Chip	Yes	Yes	Yes
Set temperature	Yes	Yes	Yes
Preferences	Yes	No	No
More Tools	Yes	Yes	Yes
Help			
(all options)	Yes	Yes	Yes

B.2 Evaluation Software

Note: Options in parentheses are not available for files derived from published procedures. Access applies to all subordinate levels in a menu unless otherwise indicated.

Table 5.2:

	BIAadministrator	BIAdeveloper	BIAuser
File			
Open	Yes	Yes	Yes (published only)
Append Result File	(Yes)	(Yes)	No
Close	Yes	Yes	Yes
Save	(Yes)	(Yes)	No
Save As	Yes	Yes	Yes
Apply Evaluation Method	(Yes)	(Yes)	No
Save Evaluation Method As	(Yes)	(Yes)	No
Print	Yes	Yes	Yes
Audit trail	Yes	Yes	Yes
Properties	Yes	Yes	Yes
Export	Yes	Yes	Yes
Published Procedures	Yes	Yes	No
Exit	Yes	Yes	Yes
View			
Evaluation Explorer	Yes	Yes	Yes
Evaluation			
Add Sensorgram	Yes	Yes	Yes
Add QC Plot	Yes	Yes	Yes
Add Result Plot	Yes	Yes	No
Add Bar Chart	Yes	Yes	Yes
Add Report Point Table ¹	Yes	Yes	No
Add Kinetics / Affinity	Yes	Yes	No
Add Concentration Analysis	Yes	Yes	No

Add Thermodynamics	Yes	Yes	No
Add Immunogenicity	Yes	Yes	No
Add Screening	Yes	Yes	No
Add Sensorgram Comparison	Yes	Yes	No
Add Solvent Correction	Yes	Yes	No
Tools			
Custom Report Points	Yes	Yes	No
Keyword Table	Yes	Yes	Yes
Models	Yes	(Yes)	No
Kinetics Summary	Yes	Yes	Yes
Preferences	Yes	No	No
Window			
(all options)	Yes	Yes	Yes
Help			
(all options)	Yes	Yes	Yes

¹ An evaluation session may only contain one report point table item.

*

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