

# **Biacore™** Insight Database

## Installation and Management Guide

- BiacoreUserCreate
- BiacoreUserCreateMoveRename
- BiacoreUserCreateMoveRenameDelete
- BiacoreGxPadministrator
- BiacoreGxPuser
- BiacoreGxPdeveloper

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# 1 Introduction

## Biacore Insight database

Data from some Biacore™ systems is stored in a Microsoft® SQL Server® database, referred to as a Biacore Insight database. The database should preferably be hosted on a network server. A local database with limited storage capacity and security (see *Chapter 3 Microsoft SQL Server editions, on page 8* for details) can be installed together with the Biacore system software. The local database is intended primarily for service purposes, but can also be used as a temporary solution if the network database is not accessible.

Installation of a network database is the customer's responsibility.

## Scope of this document

This document describes how to install network and local Biacore Insight databases, and how to manage connections and access to the database. The document applies to Biacore systems that use a Biacore Insight database for data storage.

## Target audience

This document is intended for database administrator (DBA) staff responsible for installing and maintaining the Biacore Insight database. Information in this document is not required by persons using Biacore systems for label-free interaction analysis.

## Abbreviations

The following abbreviations are used in this document.

Abbreviation	Meaning
AD	Windows® Active Directory
DBA	Database Administrator
GxP	Collective abbreviation for GLP (Good Laboratory Practice), GCP (Good Clinical Practice) and GMP (Good Manufacturing Practice)
IT	Information Technology (referring to staff competence)
OS	Operating system

## 2 Installation overview

### Introduction

As a general recommendation, the computer where Biacore software is installed should be included in a network environment that uses Windows AD and has an acceptable average response time. The instructions in this document assume that this recommendation is followed.

### Required files

The files required for database installations are located in one `.zip` file and one `.exe` file. The `.zip` file contains the setup package for a Biacore Insight network database, and the `.exe` file is the setup program for a Biacore Insight local database. The installation packages for Biacore Insight databases and Biacore software are downloaded from <http://www.cytivalifesciences.com/edelivery>. Instructions for accessing this site are provided to the purchaser of the system.

### Installation workflow

The table below presents an overview of a complete installation.

Step	Action
1	<p>Make sure you have access to the downloaded Biacore database installation packages.</p> <p>See <i>Required files</i> above.</p>
2	<p>Make sure that an Enterprise or Standard edition of Microsoft SQL Server is installed on a network server.</p> <p>See <i>Chapter 3 Microsoft SQL Server editions, on page 8</i> for information about the editions. Installation instructions can be obtained from Microsoft.</p>
3	<p>Create one or more network Biacore Insight databases, and upgrade existing Biacore databases.</p> <p>See <i>Chapter 5 Create or upgrade a network database, on page 16</i>. For a GxP environment, see also <i>Chapter 8 Installation in a GxP environment, on page 30</i>.</p>
4	<p>Set up user access to the network database(s).</p> <p>See <i>Section 6.1 Set up Windows accounts and groups, on page 19</i> and <i>Section 6.2 Set up database logins, on page 20</i>. For a GxP environment, see also <i>Chapter 8 Installation in a GxP environment, on page 30</i>.</p>

<b>Step</b>	<b>Action</b>
5	(Recommended) Make sure that a connection to the network database can be created from a network computer using Biacore software. <i>See Section 6.3 Set up connection between software and database, on page 24.</i>
6	(Optional) Install a local Biacore Insight database, preferably only for service purposes. <i>See Chapter 7 Local database (optional), on page 26.</i>

## 3 Microsoft SQL Server editions

### Introduction

Microsoft SQL Server is available in Enterprise, Standard and Express editions.

This chapter provides information concerning the choice of a suitable edition. More details can be obtained from Microsoft.

### SQL Server editions

Relevant characteristics of the different SQL server editions are listed in the following table.

	Enterprise	Standard	Express
Maximum database size	524 PB	524 PB	10 GB
Computing capacity	OS maximum	4 sockets or 24 cores	1 socket or 4 cores
Maximum memory	OS maximum	128 GB	1 GB
Database mirroring	Yes	Yes	No
Smart encrypted backups	Yes	Yes	No
Auditing (tracking and logging events handled by the Database Engine)	Yes	Yes	No
Built-in backup scheduler	Yes	Yes	No
Available free of charge	No	No	Yes

**Note:** *The expected database size is 1 to 10 GB per instrument per year, depending on the number of runs and the data collection rate.*

**Note:** *Multiple Biacore Insight databases can be created on the same server if required.*

### Network database

The following versions of SQL Server Standard and Enterprise editions can be used to host the Biacore Insight network database:

- SQL Server 2017
- SQL Server 2019

**Note:** *Older versions of SQL Server are not recommended, as Microsoft does not support them.*



These editions provide large storage capacity and built-in backup schedules. Several instruments can store run data in the same server. An instrument can also store run data (from different runs) in different databases/servers. If you need to move data, for example from an existing server to a new server, use the Export/Import function in the Biacore software.

**Note:** *Activity history cannot be moved between databases. The activity history is stored in the database to which the control software is connected during the activity.*

**Note:** *The SQL Server Express edition should not be used for the network database due to its limited storage capacity and functionality.*

## Local database

If a local database is installed, it is hosted on the SQL Server 2019 Express edition, which is included in the local setup package. It should be installed on the computer connected to the Biacore instrument.

# 4 Database security

## Introduction

This chapter contains basic security information.

## In this chapter

<b>Section</b>		<b>See page</b>
4.1	Security concepts	11
4.2	Roles	14

## 4.1 Security concepts

### Introduction

This section describes the basic concepts of Windows-based database security used by Microsoft SQL Server, and the Windows-based software security used by the Biacore software.

### Windows authentication

In Biacore systems that use Windows authentication for login, a single login dialog provides access to both the software and the database. Standard Windows user accounts are used for authentication.

Any Windows local or AD account can log in to the Biacore software, independently of the Windows account logged in to Windows OS, provided that the account logging in to the software is able to access the database.

Integrated Windows authentication provides the following features:

- All user management including passwords is handled in Windows, and the security level can be controlled by granting access to AD accounts only.
- The database connection string (see *Section 6.3 Set up connection between software and database, on page 24*) does not contain any user credentials.
- Users can be organized in Windows groups to manage access to the software and access rights in the database.

### Security concepts in SQL Server

The following table explains the different levels at which SQL Server security can be managed. General information about SQL Server can also be obtained from Microsoft.

Term	Explanation
Windows user account	<ul style="list-style-type: none"> <li>• defined as an AD network account, or a local account</li> <li>• used for login to Windows and for authentication in Biacore software</li> <li>• managed by IT administrator</li> </ul>

## 4 Database security

### 4.1 Security concepts

Term	Explanation
Windows group	<ul style="list-style-type: none"><li>• AD groups for a network database are defined on the domain controller somewhere in the network</li><li>• local groups for a network database are defined on the server database host</li><li>• local groups for a local database are defined on the local database host</li><li>• used to organize Windows user accounts to simplify management of access rights</li><li>• managed by IT administrator</li></ul>
Database login	<ul style="list-style-type: none"><li>• defined on a database server</li><li>• provides access to a database server</li><li>• maps to database users in a number of databases on the database server</li><li>• does not accompany a database that is moved to a different server</li></ul>
Database user	<ul style="list-style-type: none"><li>• defined in the database and assigned membership in database roles</li><li>• provides access to databases</li><li>• accompanies a database that is moved to a different server</li></ul>
Database role	<ul style="list-style-type: none"><li>• specifies rights to elements in a database</li><li>• required in SQL Server for implementation of access rights</li><li>• Biacore database roles are set up by installation script for Biacore Insight database</li></ul>

**Note:** *Do not confuse Windows user accounts with SQL Server database login or database users.*

## Accessing network databases

In order to use Biacore software with a network Biacore Insight database, the following is required:

- The Windows user must be able to access the network server where the database is stored.
- The Windows user must be mapped (via a database user, either individually or through a Windows group) to a database login for the particular database.
- The database login must give the Windows user membership in database roles with appropriate access rights to the database.

**Note:** *Access to the Biacore Insight database is implemented using Windows impersonation. All Windows user accounts that require access to the database must be set up by the database administrator as described in this document.*

## **Backup considerations**

Database backup and disaster recovery strategy should be handled by the IT/DBA team at the site.

A full recovery model for database backup is recommended.

## 4.2 Roles

### Introduction

This section lists all roles that are used for accessing Biacore databases. All database roles with Biacore in the name are created by the installation script.

### Required server role

Each user needs membership in the server-level role **public**, to get connect permission to Biacore databases.

Server role	Access
<b>public</b>	This role gives connect permission to all Biacore databases.

### Required database role

Each user needs membership in one of the following three Biacore database roles, to get access within a specific Biacore database.

**Note:** Do not use the database roles **db\_datareader** and **db\_datawriter**.

Database role	Access
<b>BiacoreUsersCreate</b>	This role is allowed to read and create folders, runs, methods, evaluations, and evaluation methods.
<b>BiacoreUsersCreate-MoveRename</b>	This role is allowed to do the same as the role above, but is also allowed to rename and move folders, runs, methods, evaluations, and evaluation methods.
<b>BiacoreUsersCreate-MoveRenameDelete</b>	This role is allowed to do the same as the role above, but is also allowed to delete folders, runs, methods, evaluations, and evaluation methods.

### GxP database roles

To be able to start the system software with the GxP extension, each user also needs membership in at least one of the following three GxP Biacore database roles, for that database. The database roles can be combined for increased access.

**Note:** If one of the roles below is assigned, the user cannot start the system software without the GxP extension.

Database role	Access
<b><i>BiacoreGxAdministrator</i></b>	This role gives access to the <b>Users</b> workspace that displays user details. It does not give access to the instrument.
<b><i>BiacoreGxPuser</i></b>	This role gives access to tools for performing and evaluating routine analyses using regulated procedures.
<b><i>BiacoreGxPdeveloper</i></b>	This role gives access to tools for developing and maintaining regulated procedures.

For examples of combinations of general database roles and GxP database roles, see *Chapter 8 Installation in a GxP environment, on page 30*.

For details on GxP access levels, see the *Biacore Insight GxP Handbook*.

## Other roles

Do not use other roles within Biacore databases.

# 5 Create or upgrade a network database

## Introduction

As a general recommendation, the computer where Biacore Insight software is installed should be included in a network environment that uses Windows AD and has an acceptable average response time. The instructions in this document assume that this recommendation is followed.

Familiarity with **SQL Server Management Studio** is assumed.

## Set up a Biacore Insight database

Follow the instructions below to create or upgrade a network Biacore Insight database.

Step	Action
1	Make sure you have access to the <code>.zip</code> file that contains the network database package. Unzip the file to find the <code>Installation-ScriptDb.sql</code> file.
2	If an existing Biacore database is to be upgraded, make sure that you have a fresh backup of the database and that no users are logged in to the database.
3	Start <b>SQL Server Management Studio</b> and connect to the database server as a user with administrator rights to the server.
4	Create a new database with an appropriate name, or select an existing Biacore database.
	<b>Note:</b> <i>Multiple Biacore Insight databases can be created on the same server if required.</i>
5	Run the script <code>InstallationScriptDb.sql</code> in a query window connected to the intended database.
6	(Recommended) Set the database recovery model to <b>Full</b> .

**Note:** *After upgrading a Biacore database, remember to check the database roles for all database logins, see Section 6.2 Set up database logins, on page 20.*

**Note:** *Handling disaster recovery strategy and making sure that the database has sufficient available storage is the responsibility of the IT/DBA team at the customer site.*



## Collation

The recommended collation for the Biacore Insight database is ***Finnish\_Swedish\_CI\_AS***, which supports Unicode.

# 6 Set up access to a network database

## Introduction

This chapter describes the recommended procedures for setting up access to a Biacore Insight network database.

**Note:** *Set up access from AD accounts only.*

## In this chapter

Section		See page
6.1	Set up Windows accounts and groups	19
6.2	Set up database logins	20
6.3	Set up connection between software and database	24

## 6.1 Set up Windows accounts and groups

### Introduction

Integrated Windows authentication is used for access control to the Biacore software, which in turn provides access to the Biacore Insight database. Access requires that Windows accounts are mapped to a database login, either individually or through membership in a Windows user group.

Groups can be set up either as AD groups, or as local groups on the database server. Contact your IT department if you want to use AD groups. This section describes how to create and manage local groups.

If you intend to set up multiple databases on the same server, accessible to different groups of users, create access groups for each database.

**Note:** *The Windows user is recorded in the database as the creator of runs, evaluations and so on, and can be used as a search parameter in the software. Shared user accounts are generally not recommended.*

### Set up a local Windows group

Follow the steps below to create a local user group on the database server. Repeat the procedure to create more groups.

Step	Action
1	Run the <b>Local Users and Groups</b> Windows application ( <i>lusrmgr.msc</i> ) on the network server.
2	Open the <b>Groups</b> folder.
3	Choose <b>Action</b> → <b>New Group</b> and enter a suitable group name. Enter a description if required.
4	Add AD accounts to the group.

### Updating local Windows groups

If an existing network database is upgraded that uses local Windows groups defined with regard to the database roles in the previous installation (full access and restricted access), adjust the procedure in this section to update the local Windows groups. You can adjust the names of the groups and divide the groups to make use of the three database roles in the updated database (plus three more, belonging to the GxP extension) that are available with this version of Biacore Insight database.

## 6.2 Set up database logins

### Introduction

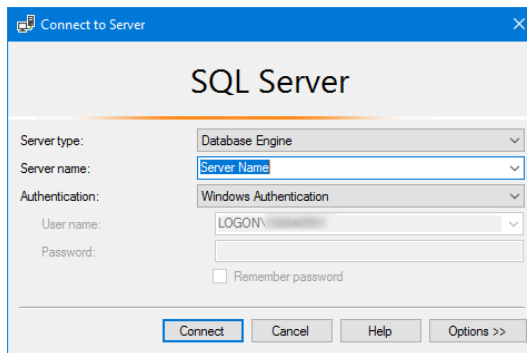
This section describes how to set up access to a Biacore Insight network database using Windows authentication. The procedure should be done by the DBA.

### Create or update a database login

Follow the steps below to create or update a database login for an AD account or group.

Step	Action
------	--------

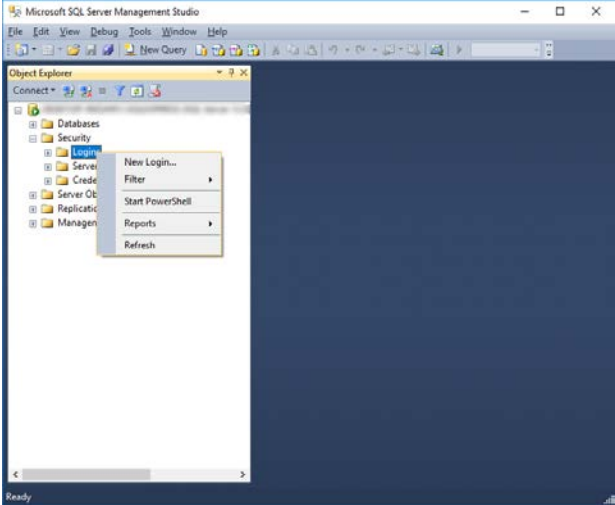
- |   |   |
|---|---|
| 1 | If an existing login is to be updated, inform involved users before you start. All changes to the login will take effect immediately. |
| 2 | Start <b>SQL Server Management Studio</b> , select your server and click <b>Connect</b> .   |



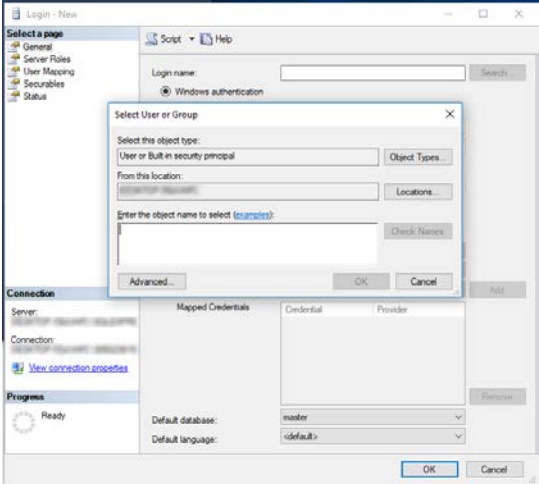
- |   |  |
|---|--|
| 3 | If an existing login is to be updated, select the login in the list under <b>Security</b> → <b>Logins</b> , and go directly to <b>Step 9, Select the User Mapping page ...</b> |
|---|--|

**Step Action**

- 4 In the **Object Explorer** pane, open the **Security** folder. Right-click on **Logins** and select **New Login**.



- 5 Select **Windows authentication**, and click **Search** next to the **Login name:** field.

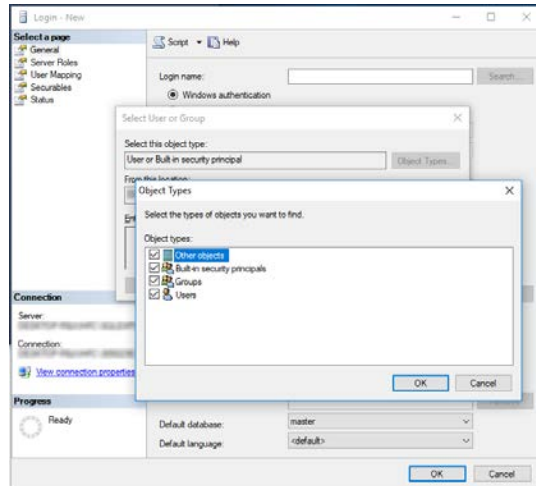


## 6 Set up access to a network database

### 6.2 Set up database logins

#### Step Action

- 6 If you are setting up a login for a group, click **Object Types** and tick the **Groups** checkbox, then click **OK**. This will make groups visible.



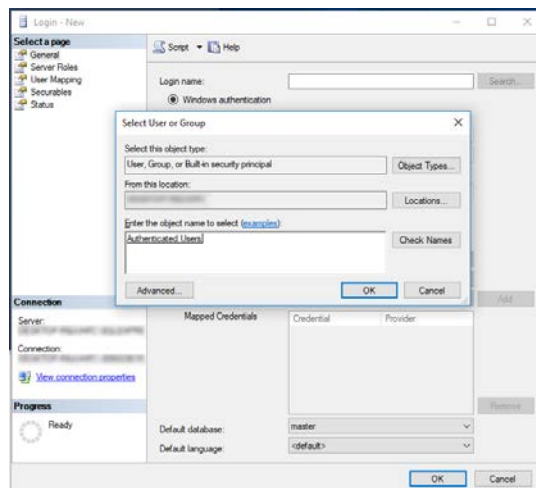
- 7 Enter the name of the AD account or group as the object name in the **Select User or Group** dialog. Click **Check Names**.

#### **Note:**

If you receive a message that the object cannot be found, check your spelling.

#### **Note:**

The group **Authenticated users** that is shown in the images is only used if all authenticated users are to be given the same access level.



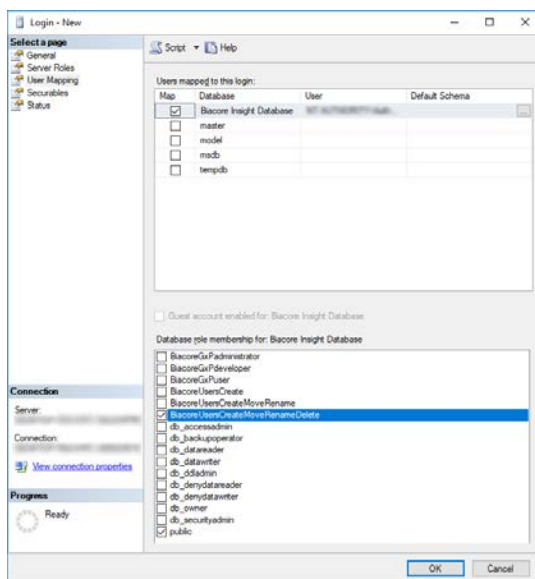
Step	Action
------	--------

8	Click <b>OK</b> .
---	-------------------

*Result:*

The **Login name**: field is completed automatically.

9	Select the <b>User Mapping</b> page for the login. Tick the checkbox for your Biacore Insight database in the upper field, and tick the checkboxes for role membership according to requirements in the lower field.
---	--



Some examples for a non-GxP environment are shown in the table below. For examples for a GxP environment, see *Chapter 8 Installation in a GxP environment, on page 30*.

Example	Roles
User	<ul style="list-style-type: none"> <li>• <b><i>BiacoreUsersCreate</i></b></li> <li>• <b><i>public</i></b></li> </ul>
Experienced user	<ul style="list-style-type: none"> <li>• <b><i>BiacoreUsersCreateMoveRename</i></b></li> <li>• <b><i>public</i></b></li> </ul>
Administrator	<ul style="list-style-type: none"> <li>• <b><i>BiacoreUsersCreateMoveRenameDelete</i></b></li> <li>• <b><i>public</i></b></li> </ul>

10	Click <b>OK</b> in all open dialogs.
----	--------------------------------------

- 6 Set up access to a network database
- 6.3 Set up connection between software and database

## 6.3 Set up connection between software and database

### Introduction

Connection between the Biacore software (e.g., Biacore 8K Control software or Biacore Insight Evaluation software) and the network database is established when the user starts the Biacore software.

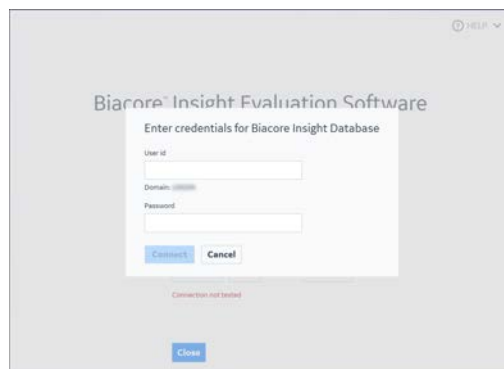
Prepare to inform the user of the correct **Server name** and **Database id** before every user's first connection. After the first connection, this information is recalled and only user credentials are needed to connect to the database.

### Perform first connection

After installation or upgrading a network database, it is recommended to verify that a user can connect to the network database.

Follow the steps below to connect to a network database for the first time.

Step	Action
1	Start the Biacore software, and click the pen icon next to <b>Database</b> , to show fields with database information.
2	Under <b>Connection details</b> , enter <b>Server name</b> , <b>Database id</b> , and a suitable <b>Alias</b> . Click <b>Connect</b> .
3	Enter valid credentials and click <b>Connect</b> to test the connection.



- 4 Click **Save** to save the new connection.
- 5 Click **Close** to close the fields with database information.
- 6 (Optional) To continue starting the software, make sure the correct license server and software extensions are selected, enter your credentials and click **Log in**.



## 6 Set up access to a network database

### 6.3 Set up connection between software and database

For more information about starting the system/software, see the documentation for your Biacore system.

# 7 Local database (optional)

## Introduction

A local database can be installed for service purposes. It can also provide alternative storage and instrument control functions if the network server is temporarily inaccessible.

This chapter describes how to install, upgrade, and access a local database.

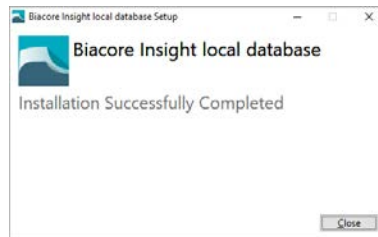
## Installation procedure

Follow the steps below to install a local Biacore Insight database. The procedure will install SQL Server Express and any other required components.

**Note:** *The local database should be installed on a computer that is connected to a Biacore instrument.*

Step	Action
------	--------

- |   |   |
|---|---|
| 1 | Run <code>Biacore Insight Local Database Setup.exe</code> , accept the license terms and click <b>Install</b> .     |
| 2 | Restart the computer, log in using the same user account, and allow the setup to finalize. This may take some time. |



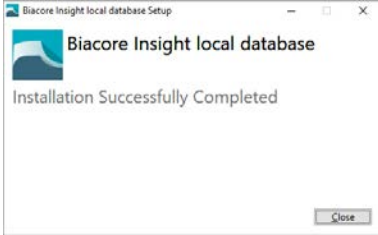
**Note:** *All users have full access rights after the installation. It is recommended to set up restricted access, see [Setting up restricted access](#), on page 27.*

## Upgrade a local database

Follow the steps below to upgrade an existing local database.

Step	Action
------	--------

- |   |  |
|---|--|
| 1 | Make sure you have a fresh backup of the database. |
|---|--|

Step	Action
2	Run <code>Biacore Insight Local Database Setup.exe</code> , accept the license terms and click <b>Install</b> . If correct versions of .NET framework and SQL Server Express already are installed, they will not be re-installed.
3	Restart the computer, log in using the same user account, and allow the setup to finalize. This may take some time.
	
4	If a database using Biacore 8K version 1.2 or Biacore Insight Evaluation version 1.0 was upgraded, the Windows groups <b><i>Biacore8KFullAccessUsers</i></b> and <b><i>Biacore8KLimitedAccessUsers</i></b> still remain. It is recommended to move users with restricted access to new Windows groups, see <i>Setting up restricted access, on page 27</i> , and remove the two old groups.
5	If the database had users with restricted access, other than mentioned in the previous step, make sure their access is still correct.
6	If a database named "BIACORE8K" using Biacore 8K version 1.1.1 and earlier was upgraded, note that this database not is renamed during the upgrade and is still named "BIACORE8K".

## Setting up restricted access

Permission to delete, move or rename data can be restricted to certain users, and it is possible to set up database security so that selected Windows users can be excluded from accessing the database at all. This can be done by populating the groups below, or by following the instructions for the network database, see *Section 6.2 Set up database logins, on page 20*. The following local Windows groups (with corresponding logins) are created by the installation script as an aid in setting up restricted access:

Local Windows group	Assigned database/server role
<b><i>BiacoreLimitedAccessUsers</i></b>	<b><i>BiacoreUsersCreate</i></b>
<b><i>BiacoreEditorialAccessUsers</i></b>	<b><i>BiacoreUsersCreateMoveRename</i></b>
<b><i>BiacoreFullAccessUsers</i></b>	<b><i>BiacoreUsersCreateMoveRenameDelete</i></b>

Local Windows group	Assigned database/server role
<b>SQLServerDatabaseAdministrators</b>	<b>sysadmin</b>

Access restriction based on object ownership or type (for example, denying access to run methods created by a specific user) is not supported.

## Recommended changes to default local database configuration

When installing a local Biacore Insight database for the first time, the Windows user group **Authenticated Users** is assigned to the local Windows groups **BiacoreFullAccessUsers** and **SQLServerDatabaseAdministrators**.

**Note:** *This results in all Windows users having access to the local Biacore Insight database, with database administrator privileges.*

Follow the steps below to replace the default configuration with the recommended configuration.

Step	Action
1	Remove <b>Authenticated Users</b> from <b>BiacoreFullAccessUsers</b> and assign the relevant Biacore system users to the appropriate database role.
2	Assign at least one Windows or AD user as SQL Server administrator.
3	Remove <b>AuthenticatedUsers</b> from <b>SQLServerDatabaseAdministrators</b> .
4	Add the assigned SQL Server administrators to <b>SQLServerDatabaseAdministrators</b> . The SQL Server administrator should preferably not be a Biacore system user, as the role will have full database privileges.

**Note:** *When performing future updates of the local Biacore Insight database, the setup program must be run using an account which is part of **SQLServerDatabaseAdministrators**.*

**Note:** *Updates to the local Biacore Insight database do not change assigned database roles.*

## Accessing a local database

A local database is accessed from the Biacore software login dialog using the following settings:

Parameter	Value
<b>Server name</b>	<b>.\SQLEXPRESS</b>
<b>Database id</b>	<b>Biacore Insight Database</b> <sup>1</sup>

<sup>1</sup> If the database has been upgraded from Biacore 8K version 1.1.1 and earlier, the **Database id** is **BIACORE8K**.

## Accessing a local database from another computer

If you want to access a local database from another computer, the firewall settings on the computer that hosts the database must allow the required communication.

The following information can be necessary in order to adjust the firewall settings.

Parameter	Value
Server name	<b>Full computer name</b> of the computer hosting the local database, found in <b>System properties</b> <sup>1</sup> .
Database id	<b>Biacore Insight Database</b> <sup>2</sup>
Program location	Usually C:\Program Files\Microsoft SQL Server\MSSQL15.MSSQLSERVER\MSSQL\Binn\Sqlservr.exe <sup>3</sup>
TCP port (for SQL server communication)	1433
UDP port (for SQL Server Browser service)	1434

<sup>1</sup> System properties are found in the **System** item in the Windows **Control Panel**.

<sup>2</sup> If the database has been upgraded from Biacore 8K version 1.1.1 and earlier, the **Database id** is **BIACORE8K**.

<sup>3</sup> The path depends on the SQL Server version and database instance name. For example, MSSQL15.SQLEXPRESS is the folder name for SQL Server 2019 and the instance name SQLEXPRESS.

## Backup considerations

If a local database is used for more than service purposes, a database backup and recovery strategy should be handled at the site. A full recovery model for database backup is recommended.

# 8 Installation in a GxP environment

## Introduction

This chapter contains recommendations for installation in a GxP environment.

## Separate database

It is recommended to set up a separate database for GxP work.

## GxP access

All logins connected to a GxP database must have membership in at least one **BiacoreGxP...** database role on the GxP database, in addition to a general Biacore database role on the GxP database, and the **public** server role.

Examples of role combinations are shown in the table below.

Example	Role
Administrator in a GxP database	<ul style="list-style-type: none"> <li>• <b>BiacoreGxPadministrator</b></li> <li>• <b>BiacoreUsersCreateMoveRenameDelete</b></li> <li>• <b>public</b></li> </ul>
User in a GxP database	<ul style="list-style-type: none"> <li>• <b>BiacoreGxPuser</b></li> <li>• <b>BiacoreUsersCreate</b></li> <li>• <b>public</b></li> </ul>
Developer in a GxP database	<ul style="list-style-type: none"> <li>• <b>BiacoreGxPdeveloper</b></li> <li>• <b>BiacoreUsersCreate</b></li> <li>• <b>public</b></li> </ul>

For information about access handling and available roles, see *Chapter 4 Database security, on page 10*.

For details on GxP access levels, see the *Biacore Insight GxP Handbook*.

# 9 Quick guide for upgrading a network database

## Instructions

For more detailed instructions, see *Chapter 5 Create or upgrade a network database, on page 16* and *Chapter 6 Set up access to a network database, on page 18*.

Step	Action
1	Make sure that you have a fresh backup and that no users are logged in.
2	Start <b>SQL Server Management Studio</b> and connect to the database server, with administrator rights.
3	Run the script <code>InstallationScriptDb.sql</code> in a query window connected to the database to be upgraded. The script is provided in the network database installation package.
4	Make sure that correct roles are used for access, see <i>Section 4.2 Roles, on page 14</i> .

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