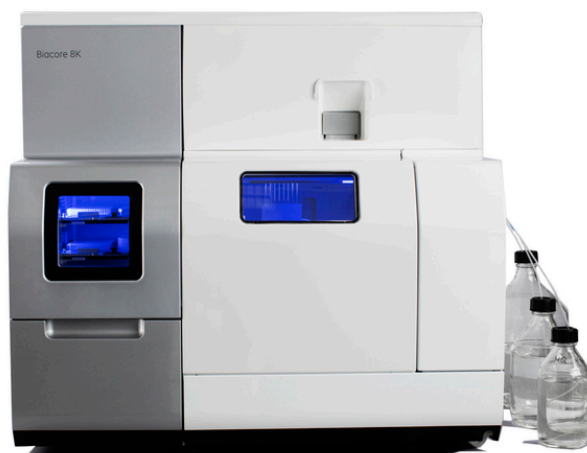


# Biacore™ 8K Control software

# Biacore™ Insight Evaluation software

## Privacy and Security Manual



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# 1 Introduction

## About this manual

This manual describes the privacy and security considerations of the use of the Biacore™ 8K Control software and Biacore Insight Evaluation software, which are dependent on the Biacore Insight database. The two applications are referred to as Biacore 8K & Insight software in this document.

## Purpose of this manual

This manual describes the expected intended use of Biacore 8K & Insight software, the privacy and security capabilities included, and how these capabilities are configured.

## Scope of this manual

The document is valid for Biacore 8K Control software, and Biacore Insight Evaluation software versions 4.0 and higher, and for Biacore Insight database versions 2.1 and higher.

## Introduction to privacy and security

This manual assumes that the reader understands the concepts of privacy and security. Security protects both system and information from risks to confidentiality, integrity, and availability. Security and privacy work together to help reduce risk to an acceptable level. In healthcare, the privacy, security, and safety must be balanced, relating to the intended use of the product.

The customer is encouraged to use risk management procedures to assess and prioritize privacy, security, and safety risks. Using the risk management, the customer can determine how to best leverage the capabilities provided within the product.

## Product description

The Biacore 8K/8K+ system is a system for real-time label-free analysis of molecular interactions. The system consists of one or more Biacore 8K/8K+ instrument, the Biacore 8K Control software, and Biacore Insight Evaluation software installed on multiple computers connected to a common database server with the Biacore Insight database installed.

The Biacore Insight Evaluation software is also sold separately for analysis to be used together with the Biacore T200 and S200 instruments. The run files from these instruments can be imported into the Biacore Insight database.

With the GxP extension, a GxP workflow is supported managing regulated procedures, regulated runs, and regulated evaluations based on three different user roles.

**Note:** *The Biacore 8K & Insight software is not a medical device and shall not be used in any clinical procedures or for diagnostic purposes.*

## Safety notices

This user documentation contains safety notices concerning the safe use of the product. See the definition below.



### **NOTICE**

**NOTICE** indicates instructions that must be followed to avoid damage to the product or other equipment.

## Contact information

For specific privacy and security inquiries, use the contact form found at [cytiva.com/contact](https://www.cytiva.com/contact).

## 2 Privacy and security in the environment

Biacore 8K & Insight software has been designed for an intended use with the following expectations of privacy and security protection, that should be included in the environment where Biacore 8K & Insight software will be used:

- The Biacore 8K & Insight software is designed to reside on computers that are members of Microsoft® Active Directory™ in the customer network.
- For network database installations, all users of the Biacore 8K & Insight software must be members of Active Directory. For local database installations the application depends on either Active Directory or local Windows® accounts. It is recommended to use a central database as this provides higher security, possibility to share data between systems, and larger storage capacity. 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.
- Access to the Biacore 8K & Insight software is gained through membership in one of the Biacore Insight database roles.
- Biacore 8K & Insight software users shall not have Windows administrator privileges as this enables the user to bypass security configurations.

# 3 Authentication, authorization and audit logging

## About this chapter

Biacore 8K & Insight software includes a broad assortment of capabilities to enable privacy and security. This chapter describes the ability and use of these privacy and security capabilities.

## In this chapter

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3.2	Audit logging and accountability controls	8

## 3.1 Access controls

### Introduction

The access control on Biacore 8K & Insight software is used to help control access to customer information on the system. Access control includes user account creation, assigning the privileges, and other features, such as assigning privileges to Active Directory users in Biacore Insight database.

### Identity provisioning

The provisioning of user accounts requires the steps of account creation, maintenance, and removal of the account when it is no longer needed. A user account is created to be used by a specific individual. This user account is associated with access rights, and is recorded in system security log files.

For Biacore 8K & Insight software, the provisioning of users is performed through Active Directory for domain accounts, and through Windows for local accounts. Use of Active Directory is recommended as it provides higher security. Active Directory and Windows provide event logs. Monitoring of these event logs is recommended to early discover any computer security compromises.

### User authentication

The user authentication step verifies that the user attempting to access the system is indeed the user associated with the specific account. This section describes the administration of the authentication system.

- When starting the Biacore 8K & Insight software, the user must log on to the application with the username and password for an Active Directory or Windows user account.
- Only members of one of the BiacoreUsers roles in the Biacore Insight database can log on to the applications. For information about BiacoreUsers roles, refer to *Biacore Insight Database Installation and Management Guide, 29287249*.
- A successful logon to the Biacore 8K & Insight software will result in the application process being run as the user that logged on.
- The database connection string does not contain any username or password, database access is based on the Active Directory users access rights to the specified database.

### Assigning access rights

Assigning access rights is the administrative process for connecting permissions with user accounts. This is performed by a database administrator or Active Directory administrator who can assign users to different database roles for the Biacore Insight database.

Active Directory users who are not members of any of the BiacoreUsers database roles do not have read or write access to the database.

## 3.2 Audit logging and accountability controls

Privacy and security information logging and control provide accountability through security surveillance, auditable records, and reporting.

The Biacore 8K & Insight software does not have built in privacy and security audit logs, as it does not contain any means to change security settings. Audit logs can be created using Active Directory audit functionality as well as using Microsoft SQL Server® audit functionality.



## 4 Patient privacy consent management

Biacore 8K & Insight software does not handle (create, transfer, or store) patient data, therefore the patient privacy consent is not applicable to Biacore 8K & Insight software.

# 5 Information protection

## About this chapter

This chapter describes privacy and security operations, and contains guidelines for the preparation of a secure environment for Biacore 8K & Insight software.

## Defense in depth

Security operations are best implemented as part of an overall "defense in depth" information assurance strategy. This strategy is used throughout an information technology system that addresses personnel, physical security, and technology. The layered approach of defense in depth limits the risk that the failure of a single security safeguard allows the system to be compromised.

## In this chapter

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## 5.1 Network security

### Introduction

Cytiva strongly recommends that Biacore 8K & Insight software is operated in a network environment that is separated from the general purpose computing network of the owner's organization. There are many effective techniques for isolating Biacore 8K & Insight software on a secure sub-network, including implementing firewall protection, demilitarized zones (DMZs), virtual local area networks (VLANs), and network enclaves.

To assist in secure network design, the following sections describe the required network services for Biacore 8K & Insight software.

### System interconnections

The Biacore 8K & Insight software has the following system interconnections on the network:

- Biacore Insight database
- Cytiva license server
- Active directory
- File servers

It is a recommended approach to encrypt the network communication.

<b>Biacore Insight database</b>	The communication to the database has "in transit" encryption enabled by default.
<b>Cytiva license server</b>	The communication between the Biacore 8K & Insight software and the Cytiva license server is handled by a third party solution from Revenera™.
<b>Active directory</b>	The communication to the Active directory uses the LDAP protocol.
<b>File servers</b>	Any file server for file sharing is owned by the customer. Connections to file servers for saving exported files must be encrypted. In a Windows environment, make sure that the SMB3 network protocol is enabled.

### Wireless network security

Radio signals are used in a wireless network communication, therefore wireless devices require special security consideration. Effective techniques and tools exist for improving the security of wireless communication. This section describes the characteristics for wireless connections for Biacore 8K & Insight software.

Apply the appropriate company policies when accessing the Biacore Insight database via a wireless connection.

## Removable media security

Biacore 8K & Insight software does not require any removable media to operate. However, it is strongly recommended that the company policies related to removable media are applied to the computer(s) hosting Biacore clients.

## Firewall settings for Cytiva license server

The following firewall settings are used for Cytiva license server:

- Inbound traffic from Biacore 8K & Insight software clients
- No outbound traffic initiated by license server

Port	Protocol	Direction	Program	Source/Destination
Any	TCP	Inbound	BIOPHARM.exe <sup>1</sup>	Biacore 8K & Insight software client/ Cytiva license server
27000–27009	TCP	Inbound	Imgrd.exe <sup>1</sup>	Biacore 8K & Insight software client/ Cytiva license server

<sup>1</sup> Full file path: C:\Program Files (x86)\Cytiva\License server\Bin\

A Biacore 8K & Insight software client initiates a license request with Imgrd.exe, which in turn communicates with BIOPHARM.exe, and then Biacore 8K & Insight software client sends the request to BIOPHARM.exe on a dynamically assigned port.

## Firewall settings for database server

Use the following settings for the Biacore Insight database server host for inbound traffic from Biacore clients. No outbound traffic is initiated.

The settings correspond to the Windows firewall rules created by the Microsoft SQL Server installation program. The settings are the default ones, but they can be altered.

Port	Protocol	Direction	Network service	Destination
1433	TCP	Inbound		Microsoft SQL Server
1434	UDP	Inbound		Microsoft SQL Server Browser
Any	Any	Outbound	Sqlservr.exe <sup>1</sup>	N/A

<sup>1</sup> Full file path: C:\Program Files\Microsoft SQL Server\MSSQL15.SQLEXPRESS\MSSQL\Binn\sqlservr.exe

## Firewall settings on Biacore 8K & Insight software client computer

If the outgoing network traffic is blocked, apply the firewall rules as listed in the table below for the Biacore 8K & Insight software computer. The rules must be applied to the following software:

- C:\Program Files\Biacore\Biacore 8K Control Software\Biacore.8K.Control.exe
- C:\Program Files\Biacore\Biacore 8K Control Software\Biacore.Insight.LogOn.exe
- C:\Program Files\Biacore\Biacore Insight Evaluation Software\Biacore.Insight.Evaluation.exe
- C:\Program Files\Biacore\Biacore Insight Evaluation Software\Biacore.Insight.LogOn.exe

Port	Protocol	Direction	Destination
Any	TCP	Out	Cytiva license server
1433	TCP	Out	Database server
1434	UDP	Out	Database server

**Note:** *The defined database server ports are the default ports used by Microsoft SQL Server. These can be changed by the database administrator and if so, the ports opened in the firewall need to be adapted.*

## 5.2 Data storage and encryption

### Data at rest security

Biacore 8K & Insight software stores data in a persistent storage. This includes methods, results, log files, and system data. The persistent storage consists of one or more Microsoft SQL Server databases. The communication to the Microsoft SQL Server is protected by encryption, but the Biacore Insight database is not encrypted by default. It is recommended that the database administrator enables encryption at rest on the Microsoft SQL Server databases.

Exported runs, evaluations, run methods, and evaluation methods are encrypted at rest.

Exported files in Microsoft Excel™ format, Microsoft PowerPoint™ format, or PDF format are not encrypted and it is a customer responsibility to establish appropriate file management procedures.

### Recommendations for local database installation

The recommendation is to use a central database. If a local database is used, note that the local Biacore Insight database is configured by default for high accessibility, but with lower security. See *Biacore Insight Database Installation and Management Guide (29287249)* for further details.

### Data integrity capabilities

Biacore 8K & Insight software has capabilities to prevent the data from being accidentally or maliciously modified.

In a correctly configured Biacore Insight database the user will have the necessary access rights to database tables with the help of the BiacoreUsers roles.

The data for runs and regulated evaluations cannot be updated, and are thereby protected from manipulation. Users granted delete rights, if any, can however delete both runs and regulated evaluations.

However, the database administrator has full access to the database contents and may perform changes that cannot be detected by Biacore 8K & Insight software. It is therefore important for the data integrity that database administration is covered by well-established routines with data integrity in mind.

### De-identification capabilities

Biacore 8K & Insight software is not a medical device and does not handle (create, transfer, or store) patient data. Therefore Biacore 8K & Insight software does not contain de-identification (anonymization and pseudonymization) capabilities.

### Business continuity

Backup and disaster recovery routines for the Biacore Insight database is the responsibility of the customer database administrator or other applicable administrator.

The system needs to be configured and maintained in a way that continually protects privacy and security.

## 5.3 External connections

### Connection to an external computer

See [System interconnections, on page 11](#) for more information.

### Security controls provided by the cloud provider

Biacore 8K & Insight software is not hosted on a third party cloud environment. Cloud security controls are not applicable.



# 6 System protection

## Introduction

This chapter describes the guidelines for how to configure and maintain the product in a way that continuously protects privacy and security.

## Protection from malicious attacks

The computing environment is increasingly hostile, and threats continue to grow from denial of service attacks and malicious software, including computer viruses, worms, Trojan horses, and other malware. Vigilant defense on many levels is required to keep the systems free from intrusion by malicious software. In most cases, effective protection requires cooperation between Cytiva and our customers.

This product is designed to be used in an environment where commercial antivirus software is used to detect the presence of malicious software.

## Server and/or workstation security

Biacore 8K & Insight software is deployed in a customer controlled environment, hence the customer is responsible for local operational security.

## Patch management practices

Cytiva recommends that the latest updates to the operating system should always be applied.



### NOTICE

An operating system update might interrupt the operation. To prevent unexpected equipment operation, the update process should be initiated manually and only performed when the equipment is not in use.

The customer is responsible for maintaining the computer hosting Biacore 8K & Insight software. This maintenance includes at least the following:

- If a Biacore Insight database is installed, make sure that the option to receive updates for other Microsoft products is enabled when updating Windows. This will ensure that any available Microsoft SQL Server updates are installed.
- Applying updates to computer firmware and drivers.
- Applying operating system configuration changes.
- Applying operating system routine maintenance.
- Applying Biacore 8K & Insight software upgrades.

- Applying Biacore Insight database backup and disaster recovery routines.

Furthermore, any malware protection software installed must also be maintained by the customer. This maintenance includes management of patches, upgrades, configuration change, and routine maintenance. For more information about how to apply malicious software protection, see [Protection from malicious attacks, on page 17](#).

Questions or incident reports regarding cyber security related to Biacore 8K & Insight software can be done via the appointed Cytiva Key Account Manager or the Cytiva Service Personnel. Cytiva can aid with the following:

- A security enhancement request in Biacore 8K & Insight software
- A security incident related to the usage of Biacore 8K & Insight software
- General questions about the availability of online material such as documentation and similar

# 7 Remote access

## Introduction

Often the most efficient and cost-effective ways for Cytiva to provide service is to connect to Biacore 8K & Insight software remotely. Every effort is made to make sure that this connection is as secure as possible. This chapter describes the security measures for remote access connections.

## Remote connection

Cytiva provides support for the Biacore instrument by remotely connecting to the customer's computer.

## 8 Personal information collected by the product

No personal information is collected by Biacore 8K & Insight software apart from the name and ID of the user performing actions in the system.

Information stored in the database (such as run results, evaluations, methods, and the audit trail) includes the username and ID, which is required for the designed traceability features of the Biacore 8K & Insight software.

Biacore 8K & Insight software has text input fields that can be considered personal information depending on what is entered by the user.

To avoid unnecessary collection of personal information, establish instructions on how to use the text input fields.

## 9 Additional privacy and security considerations

Biacore 8K & Insight software has been designed with privacy and security functionality integrated into the core design. However, there exist privacy and security residual risks that must be mitigated when Biacore 8K & Insight software is integrated into the work environment. This section describes some risks that should be imported into the risk assessment of the deployment of Biacore 8K & Insight software for proper mitigation.

For full user access control and improved traceability the following is recommended:

- Biacore 8K & Insight software users shall not have Windows administrator privileges.
- Install the Biacore Insight database on a network server. Do not use a local database installation.
- Enable relevant database logs.
- Configure database encryption according to the Microsoft recommendations.
- Monitor the Active Directory event logs to early discover any computer security compromises.

# 10 Product security supplemental documents

## Software Bill of Materials (SBOM)

SBOM, a list of third-party software components used, is available for Biacore 8K & Insight software upon request. Contact the sales representative for a copy of SBOM.

A list of used third-party components is also available in the End-User Licence Agreement, EULA, accessible from the **About** dialog in the Biacore 8K & Insight software.

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