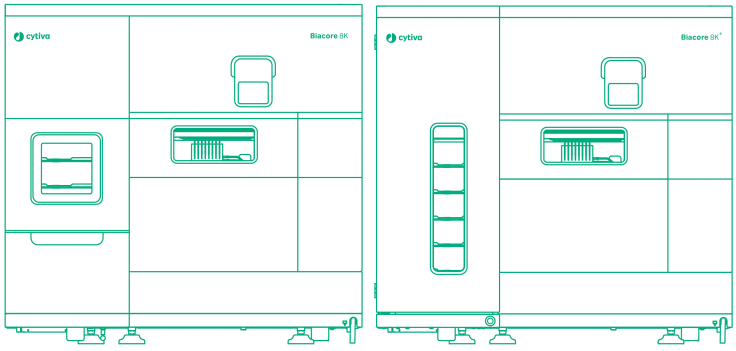
Biacore™ 8 series

Operating Instructions

Original instructions



cytiva.com

Table of Contents

1 Introduction

About this chapter

This chapter contains important user information concerning the intended use of the system, associated documentation, and a glossary.

In this chapter

1.1 Important user information

Read this before operating the product

All users must read the entire *Operating Instructions* before installing, operating, or maintaining the product.

Always keep the *Operating Instructions* at hand when operating the product.

Do not install, operate, or perform maintenance on the product in any other way than described in the user documentation. If you do, you may be exposed or expose others to hazards that can lead to personal injury and you may cause damage to the equipment.

Intended use of the product

The Biacore 8 series provides real-time label-free analysis of molecular interactions in laboratory research. The Biacore 8 series is intended for research use only and shall not be used for diagnostic purposes in any clinical or *in vitro* procedures.

Prerequisites

In order to operate the Biacore 8 series in a safe way, and according to the intended purpose, the following prerequisites must be met:

- You must read and understand the *Safety Instructions* chapter of these *Operating Instructions*.
- The system must be installed according to the instructions in the *Installation* chapter of these *Operating Instructions*.
- You should have a general understanding of the use of a personal computer running Microsoft® Windows® in the version provided with your product.
- You should be acquainted with the use of general laboratory equipment and with handling of biological materials.

A system administrator familiar with management of Microsoft SQL Server® databases is required. Familiarity with database management is not required for operation of the Biacore 8 series.

1.2 About this manual

Purpose of this manual

The Operating Instructions manual provides information needed to install, operate and maintain the product in a safe way.

Scope of this manual

These Operating Instructions apply to Biacore 8K systems and Biacore 8K+ systems. The systems differ in sample capacity (see *Sample hotel and sample compartment, on page 30*) but are otherwise closely similar. The two systems are collectively referred to as the Biacore 8 series, Biacore system (which includes hardware and software) or, when only referring to the hardware, Biacore instrument.

This document revision applies to all generations of systems within the Biacore 8 series with regards to instrument and software operations. For regulatory information, always refer to the *Operating Instructions* revision provided with your system.

Typographical conventions

Software items are identified in the text by ***bold italic*** text.

Hardware items are identified in the text by **bold** text.

In electronic format, references in *italics* are clickable hyperlinks.

Text that the user must either type exactly as shown in the manual, or that the software displays as a response (not a regular part of the graphic user interface), is shown by a monospaced typeface (for example, `Recipe Information`).

Notes and tips

Note: *A note is used to indicate information that is important for trouble-free and optimal use of the product.*

Tip: *A tip contains useful information that can improve or optimize your procedures.*

1.3 Associated documentation

Introduction

This section describes the user documentation delivered with the product, and how to find related literature that can be downloaded or ordered from Cytiva.

User documentation

The main components of the documentation for the Biacore 8 series are listed in the table below.

Translations of the *Biacore 8 series Operating Instructions* are provided in PDF format on the documentation CD inside the back cover of the printed *Operating Instructions*. Other documentation is available for download from *cytiva.com/biacore*.

Documentation	Main contents
Biacore 8 series Operating Instructions, 29286967 (this manual)	Instructions needed to install, operate and maintain the Biacore 8 series in a safe way. In the Biacore 8 series documentation, this is referred to as the *Operating Instructions*.
Biacore 8 series User Manual, 29287247	Detailed system description and instructions for preparing and running experiments. In Biacore 8 series documentation, this is referred to as the *User Manual*.
Biacore Insight Evaluation Software User Manual, 29287248	Detailed instructions for using the Biacore Insight Evaluation Software to evaluate the results of experiments with the Biacore 8 series.
Software help	On-screen assistance for using the Biacore Insight software.
Biacore 8 series Site Preparation Guide, 29338851	Requirements for space, power and other supplies, and environmental conditions for installing and running the Biacore 8 series.[1]
eLicensing Guide for Biacore Systems, 29287250	Instructions for handling electronic software licenses.[1]
Biacore Insight Database Installation and Management Guide, 29287249	Instructions for installing and maintaining the database used to store data from the Biacore systems.[1]

[1] These instructions are not required for normal use of the Biacore 8 series.

User documentation on the web

Links to laboratory guidelines, application notes, documentation and other online resources can be found on *cytiva.com/biacore*. You need to register on the website to access some of these links.

1.4 Glossary

Biacore terminology

Terms used when working with Biacore systems are explained in the following table.

Term	Meaning
Active surface	The sensor surface in the flow cell used for analysis of the interaction. This is normally flow cell 2.
Adjustment for controls	Adjustment of the sample response for changes in the surface activity during the course of an experiment, by normalizing with reference to control sample responses measured at intervals.
Analysis cycle	A sequence of injections of liquid over the sensor surface, repeated as many times as required during the course of an experiment. In the Biacore 8 series, one cycle can include analysis of up to 8 interactions, one in each channel.
Analyte	The analyte is the interaction partner in a solution, that is injected over and interacts with the ligand on the sensor surface. ***Note:*** *The analyte is not necessarily the object of the experimental investigation. For example, an antibody screening experiment can be set up where different antibodies are attached to the sensor surface as ligands, and challenged with antigen injected in solution as analyte. In this case, the object of the investigation is the ligand.*
Association phase	The phase of an analysis cycle where analyte is injected over the sensor surface and (potentially) binds to the ligand.
Baseline	The response level from which sample responses are measured. A baseline is automatically set before each injection in an analysis cycle: baselines can be set at other points in a sensorgram if required.
Blank subtraction	Subtraction of the response from a blank sample (usually buffer) from that of a test sample, to eliminate components of the response that are common to both samples.
Capture	The term ***capture*** is used to refer to the attachment of a ligand to the sensor surface by high affinity binding to an immobilized capturing molecule. Attachment by capture is normally reversible.
Capturing molecule	A molecule that is permanently attached to the sensor surface with the purpose of capturing a ligand by high affinity binding.

Term	Meaning
Channel	A single path for liquid flow over the sensor surface. The Biacore 8 series has 8 parallel channels, each consisting of two flow cells. For a given injection, the same flow settings apply to all 8 channels.
Detection spot	The area on the sensor surface where detection occurs. In the Biacore 8 series, there is one detection spot in each flow cell.
Dissociation phase	The phase of an analysis cycle immediately following the association phase, when buffer flows over the sensor surface and any bound analyte can dissociate spontaneously.
Enhancement molecule	A secondary analyte injected after the main analyte, intended to enhance the response and/or specificity of the first analyte binding.
Flow cell	The region of a channel where detection occurs. In the Biacore 8 series, each channel consists of two flow cells arranged in series. When both flow cells are addressed, liquid flows first over flow cell 1 (Fc1) and then over flow cell 2 (Fc2).
Flow channel	See C*hannel*.
Immobilization	The term ***immobilization*** is used to refer to the permanent attachment of a ligand or capturing molecule to the sensor surface, normally by covalent coupling.
Ligand	The ligand is the interaction partner attached to the surface. Attachment can be through covalent coupling (***immobilization***) or high affinity binding to an immobilized capturing molecule (***capture***). ***Note:*** *Use of the term **ligand** in Biacore contexts does not imply that the molecule is a ligand for a cellular receptor.*
Parallel flow	A flow pattern where liquid flows through all channels in the same way and at the same time. In the Biacore 8 series, the eight channels are arranged in parallel.
Reference subtraction	Subtraction of the response from the reference surface from that from the active surface, to eliminate components of the response that are common to both surfaces.
Reference surface	The sensor surface in the flow cell used as a reference. This is normally Fc1.
Regeneration	The act of removing all non-covalently attached material from the sensor surface (usually by injection of a regeneration solution) in preparation for the next analysis cycle.

Term	Meaning
Relative response	The magnitude of the SPR signal relative to a chosen reference point (usually the baseline before sample injection).
Resonance unit (RU)	The unit of measurement for the SPR response. A response of 1 RU is roughly equivalent to a change in protein concentration of 1 pg/mm^2 on the surface of Sensor Chip CM5. This correlation can differ for different molecules and on different sensor chip surfaces.
Report point	Median response over a short window (typically 5 s).
Running buffer	Buffer used for continuous flow during an experiment.
Sensor chip	A gold-covered glass slide to which one of the interactants (the ligand) is attached.
Sensor surface	The surface of the sensor chip on which the interaction being studied takes place.
Sensorgram	A plot of response against time during one analysis cycle. Normally, ***sensorgram*** refers to a single plot from one channel, either a single flow cell (reference or active) or the difference between flow cells (reference-subtracted).
Serial flow	A flow pattern where the same liquid flows through two or more flow cells, one after another. In the Biacore 8 series, the two flow cells in each channel can be addressed in series or separately.
SPR (Surface plasmon resonance)	Surface plasmon resonance, the detection principle used in Biacore instruments.

2 Safety instructions

About this chapter

This chapter describes safety precautions, labels and symbols that are attached to the equipment. In addition, the chapter describes emergency and recovery procedures, and provides recycling information.

In this chapter

Important

WARNING

All users must read and understand the entire contents of this general safety chapter, and the specific safety precautions information in each subsequent chapter of this manual to become aware of the hazards involved.

2.1 Safety precautions

Introduction

The safety precautions in this section are grouped into the following categories:

- General precautions
- Flammable liquids and explosive environment
- Personal protection
- Installing and moving
- Power supply
- Operation
- Maintenance
- Decommissioning

Definitions

This user documentation contains safety notices (WARNING, CAUTION, and NOTICE) concerning the safe use of the product. See definitions below.

WARNING

WARNING indicates a hazardous situation which, if not avoided, could result in death or serious injury. It is important not to proceed until all stated conditions are met and clearly understood.

CAUTION

CAUTION indicates a hazardous situation which, if not avoided, could result in minor or moderate injury. It is important not to proceed until all stated conditions are met and clearly understood.

NOTICE

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

General precautions

WARNING

Do not operate the product in any other way than as described in the user documentation.

WARNING

Only properly trained personnel may operate and maintain the product.

WARNING

Do not use any accessories not supplied or recommended by Cytiva.

WARNING

Waste liquids may contain hazardous or flammable substances. Take appropriate precautions to avoid spillage of hazardous waste.

WARNING

Hazardous waste. Waste liquids and used sensor chips may contain hazardous, flammable or infectious substances. Dispose of all waste products in accordance with national and local regulations.

CAUTION

Do not block the air inlet and outlet vents on the back and left side of the instrument.

Flammable liquids and explosive environment

WARNING

The product is not intended for use in locations with explosion risks or fire hazards.

WARNING

Liquids marked as flammable must not be used as running buffer or pumped reagents. Any buffer or reagent containing flammable substances must be placed in properly covered positions in micro-plates.

WARNING

Explosion hazard. To avoid building up an explosive atmosphere when using flammable liquids, make sure that the room ventilation meets the local requirements.

WARNING

Explosion hazard. Do not run any maintenance procedures that use 20% ethanol at sample compartment temperatures above 25°C.

Personal protection

WARNING

Personal Protective Equipment (PPE). Whenever packing, unpacking, transporting or moving the system, wear the following:

- Protective footwear, preferably with steel toe-cap.
- Working gloves, protecting against sharp edges.
- Protective glasses.

WARNING

Liquids in the buffer bottles or tubing may be toxic or flammable or may cause chemical burns or irritation to skin and eyes. Take appropriate precautions in the event of bottle breakage, accidental spillage and insecure fitting of tubings to bottles.

WARNING

Concentrated disinfectant solutions are corrosive. Use appropriate personal protective equipment when handling such solutions.

CAUTION

The products that are used with toxic or hazardous substances must be marked in accordance with local laws and regulations.

CAUTION

Pinch risk. Take care that fingers are not trapped by moving parts on the instrument.

CAUTION

Accidental breakage of glass bottles may leave sharp fragments and splinters that can cause cuts and abrasions.

Installing and moving

WARNING

Heavy package. The delivered instrument package is heavy. Use suitable lifting and moving equipment to handle the package.

WARNING

Heavy object. Use four or more properly trained persons or suitable lifting equipment when moving the instrument. Lifting equipment must not press on the instrument covers. All lifting and moving must be performed in accordance with local regulations.

WARNING

Use only the lifting rods provided with the system to lift the instrument.

WARNING

Heavy object. The trolley or bench on which the product is installed must have a load capacity of at least 200 kg.

CAUTION

Make sure that hands or fingers are not trapped under the instrument when the instrument is lifted or moved.

Power supply

WARNING

Protective ground. The product must always be connected to a grounded power outlet.

WARNING

Power cord. Use only the power cord delivered with the system. Do not replace the connectors on the power cord.

WARNING

Access to power switch and power cord with plug. Do not block access to the power switch and power cord. The power switch must always be easy to access. The power cord with plug must always be easy to disconnect.

Operation

WARNING

Ventilation system. A fume hood or similar ventilation system must be used when working with flammable or noxious substances.

WARNING

Heavy objects. Bottles and waste containers with capacity 5 L or more may be heavy. Take appropriate precautions when lifting.

CAUTION

Do not overload the pull-out shelf on the trolley. The maximum load capacity is marked on the shelf.

CAUTION

Do not touch the pumps while they are moving.

CAUTION

If buffer and water bottles are placed on a separate bench, make sure that the instrument and bottles are not moved apart during operation.

CAUTION

Ensure that all fluidic tubes are secured and properly connected or sealed at both ends before, during and after operation.

CAUTION

Waste tubes and containers must be secured and sealed to prevent accidental spillage.

CAUTION

Make sure that the waste container has sufficient space for maximum waste volume when the equipment is left unattended.

CAUTION

Frequent use of a computer keyboard and/or mouse may cause repetitive strain injury or disorder. Observe applicable regulations and recommendations for computer workplace ergonomics.

Maintenance

WARNING

All service and repairs, with the exception of operations explicitly described in the user documentation, must be carried out by personnel authorized by Cytiva. Do not open any covers or replace any parts unless specifically stated in the user documentation.

WARNING

The product contains mains voltage of up to 240 V AC. Disconnect mains cord before replacing fuses. Do not remove instrument covers.

WARNING

For continued protection from fire hazard, replace only with same type and rating of fuse.

WARNING

Decontaminate the instrument before performing maintenance on any instrument parts. Contact your local service representative for further information about decontamination procedures.

WARNING

Do not use more than 250 mL 20% ethanol on any single occasion for maintenance procedures.

2.2 Labels and symbols

Introduction

This section describes the nameplate, labels, and other safety and regulatory information attached to the product.

Nameplate

The nameplate provides information about the model, manufacturer, and technical data.

Description of symbols and text

The system label is located on the back of the equipment. The system label identifies the equipment and shows electrical data, regulatory compliance, and warning symbols.

The system label information is explained in the following table.

Symbol	Meaning
	**Warning!** Read the Operating Instructions before using the system. Do not open any covers or replace parts unless specifically stated in the user documentation.
Voltage	Electrical rating: • Voltage (VAC ~)
Frequency	Electrical rating: Frequency (Hz)
Max. Power	Electrical rating: Max. power (VA)
Fuse rating	Fuse rating: number of fuses, type F (fast), trip current (A), maximum voltage (V)
Mfg. Year	Year (YYYY) and month (MM) of manufacture

Safety labels and other symbols

The following labels are attached to the instrument.

Symbol /text	Placement	Description
	Inside the sample hotel.	**Caution - pinch risk.** Moving parts in the sample hotel.
	Right hand side of the peristaltic pump cover.	Waste outlet.

2.3 Emergency procedures

Introduction

This section describes how to perform an emergency stop of the Biacore 8 series in acute and controlled situations.

The section also describes the consequences of a power failure.

Acute emergency shutdown

To stop the system in an acute emergency, disconnect the mains power from the instrument.

NOTICE

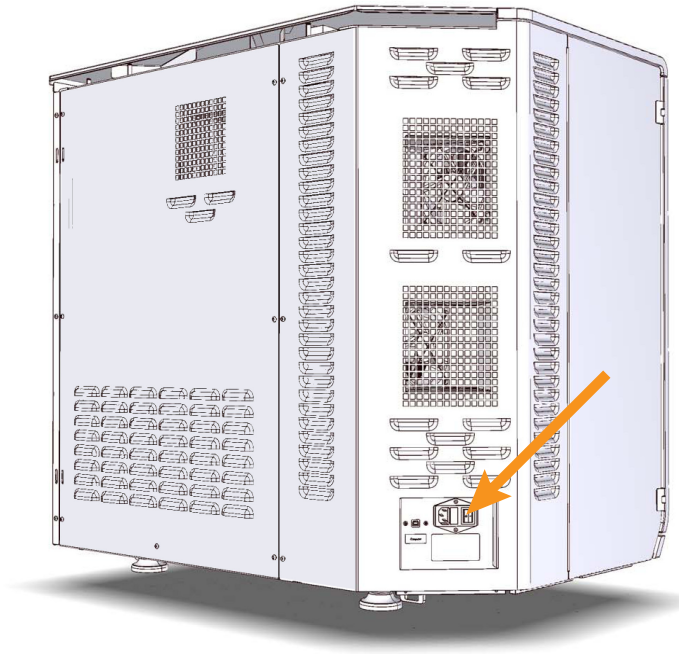
Do not use the acute emergency stop procedure unless there is a risk of injury, damage or loss of valuable material. All operations including buffer flow and data collection are stopped immediately.

Controlled emergency stop

Follow the steps below to stop the system in a controlled emergency situation.

Step	Action
1	Click ***Abort*** for the current activity in the activity queue. Choose whether to wash the flow system with buffer when the activity is aborted. You should do this if possible.

Step	Action
2	If required, switch off power to the instrument by pressing the **Power** switch to the **O** position. The power switch is located on the left-hand rear side. The illustration below shows the Biacore 8K+ instrument: the power switch on the Biacore 8K instrument is located in the corresponding position.



NOTICE

Do not leave the system in an emergency stop condition. Always follow the restart procedure if possible, to restore the instrument to normal condition.

Power failure

The following table describes the consequences of a power failure.

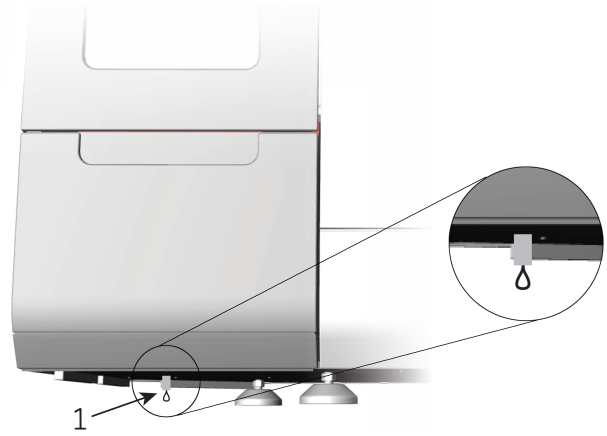
Power failure to...	will result in...
Biacore 8 system	• The run is interrupted immediately. • Data collected up to and including the last cycle completed before the power failure is saved in the results.
Computer	• The computer shuts down immediately. • Instrument operation continues for a short time (until the internal data buffer is full) and then stops. • Data collected up to and including the last cycle completed before the power failure is saved in the results.

Recover samples when the power has failed

Follow the steps below if you need to recover microplates with samples from the sample hotel before the power is restored. Recovery of samples from the sample compartment during a power failure requires assistance from a Cytiva service representative.

Step	Action
1	Disconnect the instrument from the mains power to avoid the risk that parts can move if power is restored unexpectedly.

Step	Action
2	***Biacore 8K instrument:*** If the sample hotel is locked, use a long thin screwdriver or similar tool to release the hotel door lock by pulling the release wire downwards. The release wire is situated under the instrument, directly under the sample hotel.



Part	Function
1	Sample hotel release wire

Biacore 8K+ instrument: Grip the right-hand edge of the hotel door and pull hard to force the magnetic lock on the door.

NOTICE

Power to the hotel and sample compartment is cut and any tray movement stops if the door is forced during operation.

3	Recover the microplates and close the sample hotel door.
4	Reconnect the instrument to the mains power.

Restart after emergency shutdown or power failure

Follow the steps below to restart the system after an emergency stop.

Step	Action
1	Turn on mains power if it is switched off and check that the instrument starts normally.
2	The instrument attempts to return any sample tray in the sample compartment to the sample hotel. If this does not succeed, contact Cytiva service.
3	If you need to clean the liquid handling system, eject the sensor chip and insert a maintenance chip. See *Clean and disinfect the flow system* for further instructions.

3 System description

About this chapter

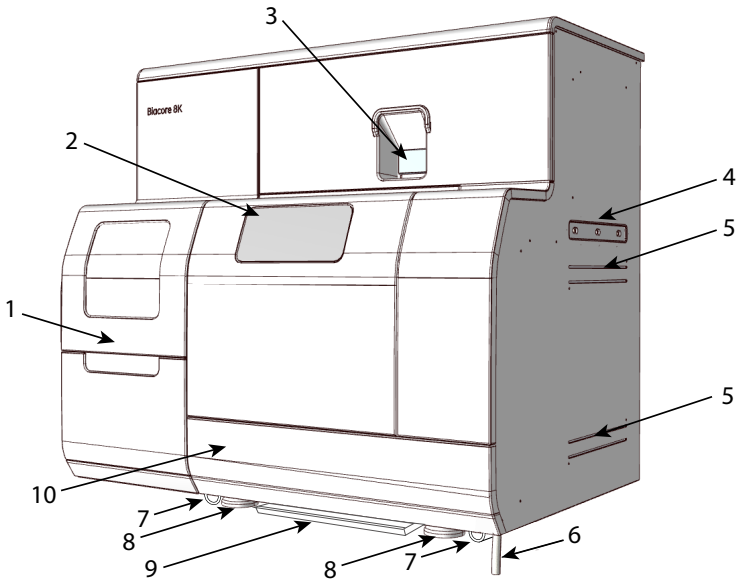
This chapter describes the Biacore 8 series.

In this chapter

3.1 Instrument components

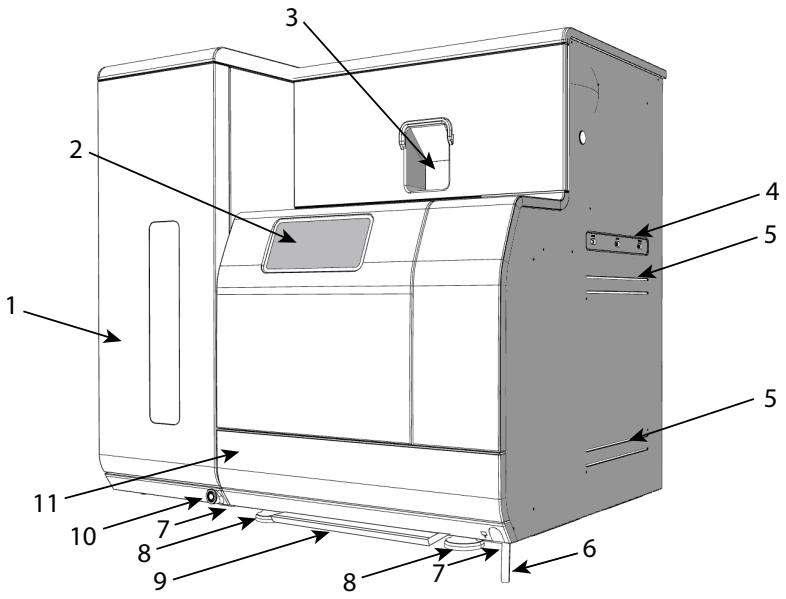
Overview

The main parts of the Biacore 8K instrument are identified in the illustration below.



Part	Function
1	Sample hotel door with window
2	Sample compartment with window
3	Sensor chip port
4	Tubing inlet panel
5	Rails for accessory holders
6	Waste tube
7	Fittings for lifting rods
8	Adjustable feet
9	Drip tray (under instrument)
10	Peristaltic pumps (behind hinged cover)

The main parts of the Biacore 8K+ instrument are identified in the illustration below.

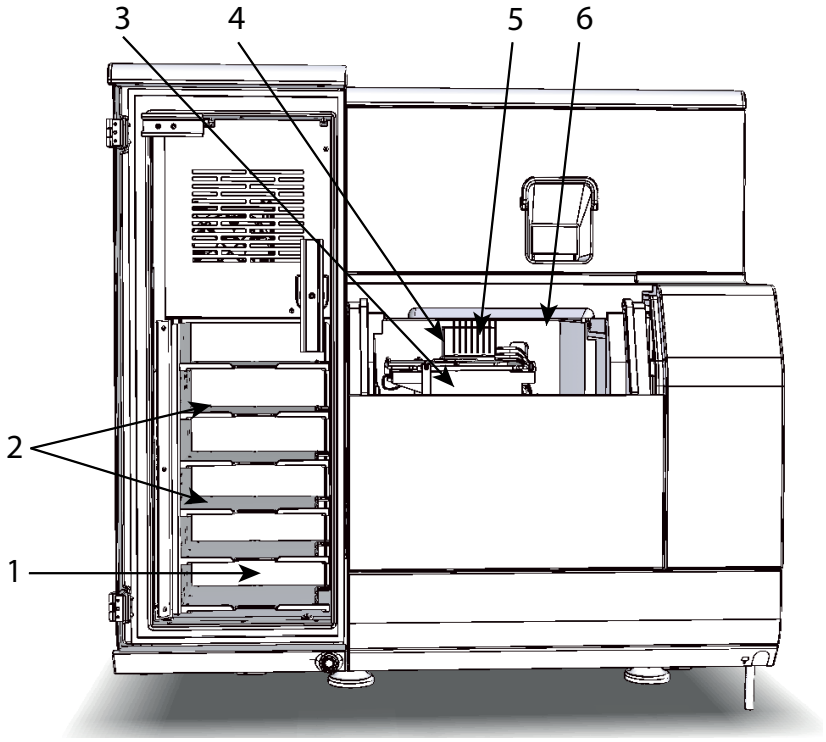


Part	Function
1	Sample hotel door with window
2	Sample compartment with window
3	Sensor chip port
4	Tubing inlet panel
5	Rails for accessory holders
6	Waste tube
7	Fittings for lifting rods (not visible in illustration)
8	Adjustable feet
9	Drip tray (under instrument)
10	Hotel door release button
11	Peristaltic pumps (behind hinged cover)

Sample hotel and sample compartment

The sample hotel is the area where trays carrying samples and reagents can be inserted by the user. There are two tray positions in the Biacore 8K hotel, referred to as ***upper*** and ***lower***. The Biacore 8K+ hotel has 6 trays, numbered 1 to 6 from top to bottom.

The sample compartment holds one tray at a time. Trays are moved from the hotel to the sample compartment, as required, by an automatic sample loading mechanism. The illustration below shows a cutaway view of the Biacore 8K+ sample hotel and sample compartment. The sample compartment is the same in the Biacore 8K instrument: the sample hotel has only two tray positions.



Part	Function
1	Sample hotel
2	Sample tray positions (2 in Biacore 8K, 6 in Biacore 8K+)
3	Sample loading carriage
4	Liquid supply block

Part	Function
5	Eight parallel injection needles
6	Sample compartment

The sample hotel and sample compartment are maintained at the same nominal temperature, set in the control software (see *Section 3.3 Temperature control, on page 40*).

Sample hotel door

The sample hotel door can be opened at any time, except when a sample tray is being transferred between the hotel and the sample compartment. Open and close the sample hotel door as described below.

Action	Biacore 8K instrument	Biacore 8K+ instrument
Open sample hotel door	Release the sample hotel door by selecting the ***Open*** function in the ***Instrument control*** work-space in the control software, then lift the door upwards. Do not attempt to open the door without first releasing it in the software.	The sample hotel door is held in place by a magnetic lock. Release the lock by pressing the release button or selecting the ***Open*** function in the ***Instrument control*** work-space in the control software.
Close sample hotel door	Close the door, then push gently on the door until it clicks into place.	Close the door gently until the magnetic lock engages.

NOTICE

Do not leave the sample hotel door open unnecessarily, as this affects the temperature regulation of the sample compartment and sample hotel.

Hotel door release button (Biacore 8K+ only)

Illumination on the sample hotel door release button indicates the status as follows:

Illumination	Status
Steady	The button is active. Pressing the button opens the hotel door.
Off	The button is inactive (because of tray transfer between the hotel and the sample compartment). Pressing the button has no effect.
Flashing	The hotel door is open.

Sample illumination

Illumination in the sample hotel and sample compartment is provided by blue LEDs. Illumination can be switched on or off from the control software. Switch the illumination off if your samples are light-sensitive.

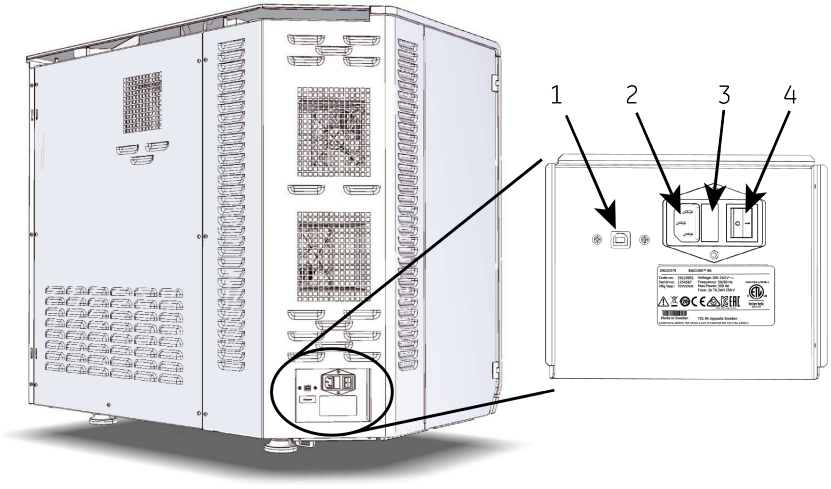
Sensor chip port

The sensor chip port is controlled from the software and cannot be opened by hand. See *Insert a sensor chip, on page 65* for further details.

Electrical connections

The electrical connection panel is located at the lower back of the instrument on the left-hand side.

The illustration below shows the Biacore 8K+ instrument. Electrical connections are in the equivalent position on the Biacore 8K instrument.



Part	Function
1	USB connector (for connection to controlling computer)
2	Mains power connector
3	Mains fuses
4	Mains power switch

3.2 Flow system

Liquid supply

Running buffer, distilled water and one optional large-volume reagent are supplied from bottles placed on the bench to the right of the instrument. Up to four different buffers can be used. Smaller bottles and tubes (up to 1000 mL) can be placed in accessory holders attached to the holder rails.

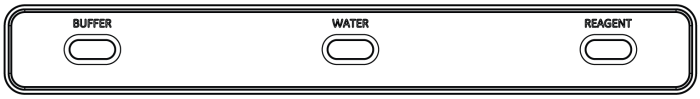
Liquid supply bottles

Glass bottles with caps (capacity 2 L and 5 L) for buffer, water and reagent are provided with the instrument. Any laboratory bottles with screw caps can be used. Bottle caps must be perforated for inlet tubing, and must be vented to prevent accumulation of over- or underpressure as the volume of liquid changes. Suitable caps are provided with the instrument.

Liquid filtering requirement

All buffers and large-volume reagents must be filtered through a 0.22 µm filter to avoid introducing unwanted particles into the flow system. Particles can lead to disturbances in the SPR response, and cause blockage or other malfunction to the microfluidic system.

Tubing inlet panel



Liquids are pumped in to the flow system through inlet tubes on the right-hand side of the instrument. The tube ports are labeled **BUFFER**, **WATER**, and **REAGENT**, used for running buffer, distilled water, and large-volume reagent respectively.

The Biacore 8K systems with Product No. 29327020 and Biacore 8K+ systems have 4 buffer inlet tubes, labeled **BUFFER A** to **BUFFER D**, providing support for up to 4 different running buffers. Buffer inlets can be selected from the control software.

TheBiacore 8K systems with Product No. 29146489 has one buffer inlet.

The **BUFFER A** (or the single **BUFFER** tube for Biacore 8K systems with Product No. 29146489), **WATER**, and **REAGENT** tubes must be supplied with liquid at all times during instrument operation, including standby. If a large-volume reagent is not used, insert the **REAGENT** tube into the distilled water bottle.

Buffer selector

Biacore 8K+ systems and Biacore 8K systems with Product No. 29327020 are fitted with a buffer selector that allows running buffer to be switched automatically between steps in the activity queue (see the *User Manual* for details). Up to four buffers are supported. Buffer cannot be switched within a step in the activity queue.

Biacore 8K systems with Product No. 29146489 have a single inlet for running buffer and do not support buffer selector functions.

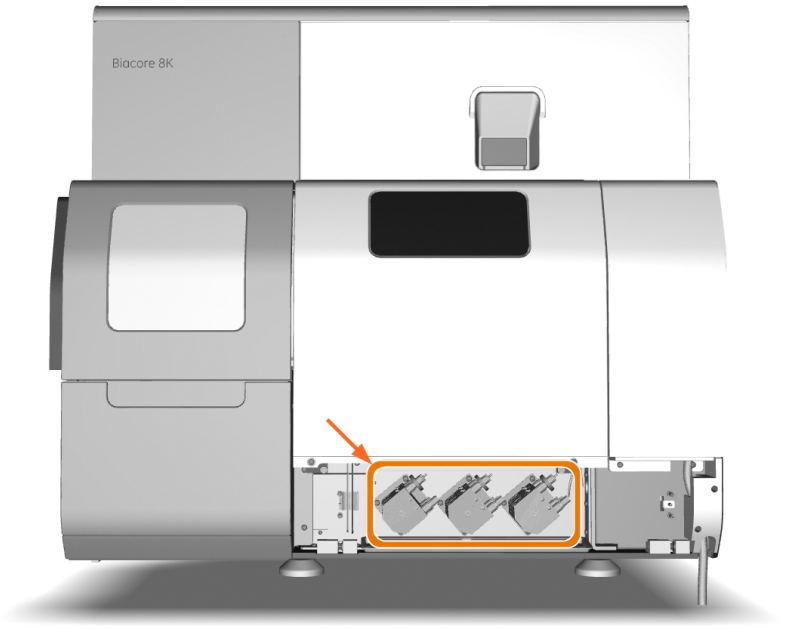
Continuous flow pumps

Continuous flow of liquid (running buffer or sample) over the sensor chip surface is managed by 16 high precision syringe pumps, housed inside the instrument. The syringe pumps are not accessible to the user.

Peristaltic pumps

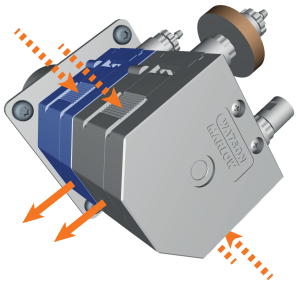
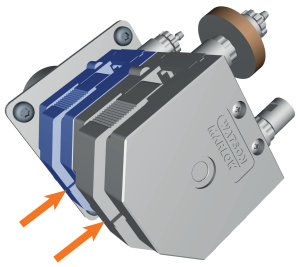
Three peristaltic pumps provide a supply of running buffer and water for washing the needles during a run, and provide regeneration or wash solution as needed. The peristaltic pumps also pump the effluent from the flow cells and liquid supply block to waste.

The peristaltic pumps are placed at the lower front of the instrument, behind a hinged panel (shown with the panel removed in the illustration below). Open the panel by pulling outwards on the top edge, to access the pumps and release the pump clamps when the instrument is shut down. The illustration below shows the Biacore 8K instrument: peristaltic pumps in the Biacore 8K+ instrument are the same.



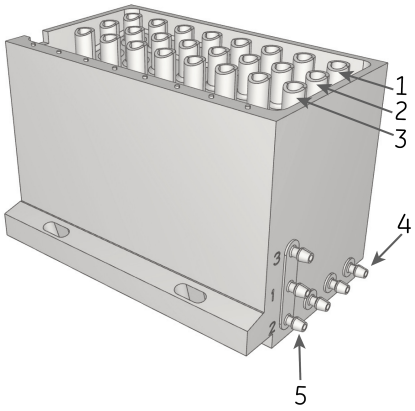
Each pump holds two pump tubes, which must be separately unclamped if the instrument is shut down and remain unused for more than 2 weeks. The pumps must be reclamped before the instrument is restarted. Follow the instructions below to open and close the pump clamps.

Note: *Always open or close the clamps in both the outer (gray) and inner (blue) pumps.*

Operation	Instruction
Open the pump clamps	Squeeze the ridged area of the clamp on both sides of the pump and pull the clamp away from the pump body.  Do this for both clamps on each pump.
Close the pump clamps	Push the clamp towards the pump body until it clicks into place. Make sure the clamp stays aligned with the pump body on both sides as the clamp is closed.  Do this for both clamps on each pump.

Liquid supply block

Buffer, water and one customer-selectable reagent are supplied to the injection needles through the ***liquid supply block*** in the sample compartment. Buffer and water are used for automatic needle wash, and the reagent can be regeneration or wash solution.



Part	Function
1	Water supply
2	Buffer supply
3	Reagent supply
4	Inlet ports
5	Outlet ports

Integrated microfluidic cartridge (IFC)

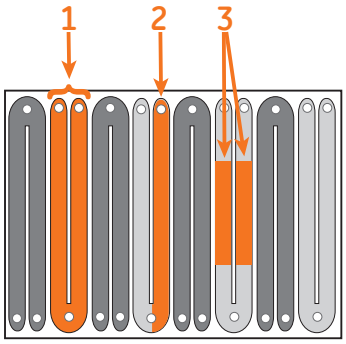
The IFC (Integrated microfluidic cartridge) consists of a series of micro-channels and membrane valves encased in a plastic housing, and serves to control delivery of liquid from the liquid supply block to the sensor chip surface. Grooves on the IFC surface that come into contact with the sensor chip form the channels when the sensor chip is docked in the instrument.

Channels and flow cells

The flow system has 8 separate channels over the sensor surface, each with two flow cells (***Fc1*** and ***Fc2***). Normally, ligand is attached to the surface in Fc2, and Fc1 is used as a reference.

The two flow cells in each channel can be addressed separately or in series. When the flow cells are addressed serially, liquid first flows over Fc1 and then over Fc2. Buffer and sample flow is controlled in parallel in all 8 channels, meaning that for any given cycle, the flow rate, sample contact times, and flow cell being addressed are the same in all channels.

A schematic representation of the arrangement of channels, flow cells and detection spots on the sensor surface is shown in the illustration below.



Part	Function
1	Channel (one of 8 indicated). Channels are shown in different gray shades for clarity.
2	Flow cell (one of 16 indicated).
3	Detection spots (two of 16 indicated).

Waste drainage

The waste tube exits from the instrument at the bottom right corner. Waste drains from the flow system through the waste tube to a waste bottle placed under the instrument. A 15 L plastic waste bottle with cap is provided.

An additional drainage tube collects condensation and any spillage or leakage from the sample compartment, and drains to a drip tray underneath the instrument. Condensed water that drains from the sample compartment normally evaporates. However, condensation volumes can be significant if the instrument is used in a humid atmosphere, particularly if there are low temperatures in the sample compartment.

In the event of leakage from the flow system in the sample compartment, the drip tray must be cleaned and, if necessary, disinfected in accordance with applicable chemical handling regulations.

Note: *The volume of liquid draining to the drip tray is normally small. Volumes can increase during operation at low sample compartment temperatures in a humid atmosphere. If significant volumes are observed under other circumstances, check the sample compartment for leaks or blockage in the waste drainage from the liquid supply block (see* *Chapter 7 Troubleshooting, on page 80**).*

3.3 Temperature control

Flow cell temperature

The temperature of the sensor chip is referred to as the ***flow cell temperature***. SPR response is highly sensitive to temperature, and precise control of the flow cell temperature is essential for reliable performance.

The flow cell temperature is controlled within the range 4°C to 40°C (maximum 18°C below ambient). The temperature is set in the control software, and runs do not start (unless explicitly allowed to do so) if the actual temperature is not equilibrated to the set value.

Sample compartment temperature

The temperature in the sample compartment can be set within the range 4°C to 40°C. The compartment can be cooled to a maximum of 18°C below ambient. The sample compartment temperature is controlled with lower precision than the flow cell temperature, and does not affect the ability to start a run.

If the sample compartment temperature differs from the flow cell temperature, injected solutions equilibrate to the flow cell temperature during transfer from the microplate to the flow cells. However, for maximum performance (particularly at high flow rates), the sample compartment temperature must be set to the same value as the flow cell temperature.

Sample hotel temperature

The temperature in the sample hotel is not actively controlled in the Biacore 8K system. The sample hotel maintains approximately the same temperature as the sample compartment provided that the sample hotel door is not opened more than necessary.

In the Biacore 8K+ system, the sample hotel is actively maintained at the same temperature as the sample compartment. For optimal temperature regulation, keep the sample hotel door closed except when handling sample trays in the hotel.

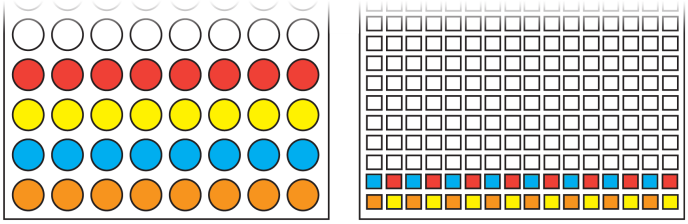
3.4 Sample handling

Microplates

Samples and low volume reagents are placed in 96- or 384-well standard or deep-well microplates. Microplate specifications and recommendations can be found in the ***Related Documents*** tab of the system's product page at *cytiva.com/biacore*.

Note: *Do not use polystyrene microplates with samples that contain DMSO.*

The 8 sample needles are spaced at a fixed distance from each other so that samples for one injection are taken from one complete row on a 96-well microplate and from every other position in a row on a 384-well plate. This is illustrated by 4 injections below, where different colors represent different injections.



The unattended processing capacity is four microplates in the Biacore 8K system and 12 microplates in the Biacore 8K+ system (see the *User Manual* for details of how runs are set up).

Microplate covers

Cover microplates immediately after preparation to prevent evaporation. The cover is penetrated by the injection needles when solution is taken from the wells. Adhesive foil and septa for covering microplates are available from Cytiva.

- Use foil for microplates where solution is taken only once from each well.
- Use septa for microplates where solution is taken more than once from any well.

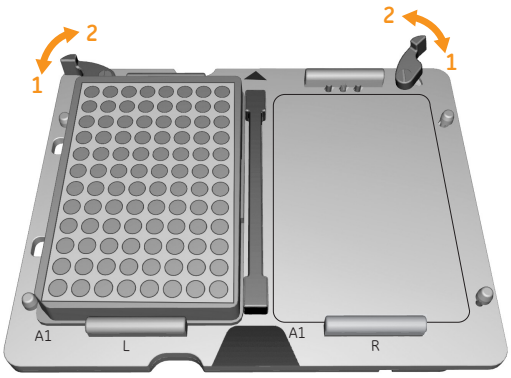
NOTICE

Place the foil or septa carefully on the microplates so that the well openings are free of adhesive. Adhesive that sticks to the injection needles seriously impair system performance.

Sample trays

Microplates are mounted on a sample tray before they are loaded into the sample hotel. Each sample tray can hold two microplates. The microplate positions are identified as **L** (left) and **R** (right).

Place the microplate on the tray as shown, with well position A1 at the front left as marked on the tray. Close the locking lever (position 1) to lock the microplate in position. Open the lever (position 2) to release the microplate. The illustration below shows a tray with one microplate locked in position: the empty position is unlocked.

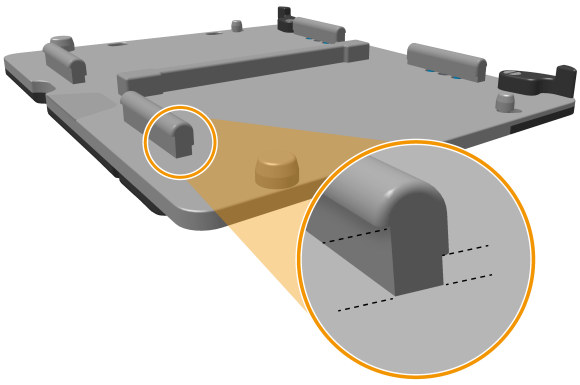


Position	State
1	Locked
2	Unlocked

Note: *Corner shapes on microplates are not standardized, and the angled corner is not always at position* **A1** *as shown in this illustration. Orient the microplate by well position and not by corner shape.*

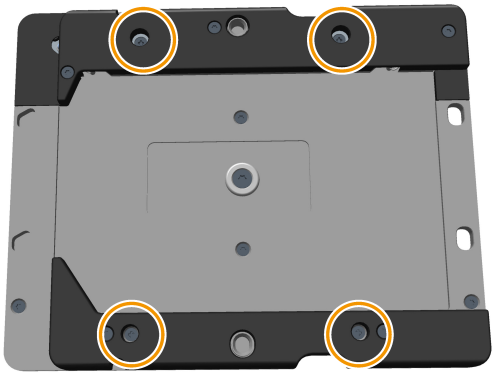
Adjusting to microplate

To accommodate different brands of microplates, the stoppers on the sample tray have two edges with different heights to be able to securely fasten both low and high microplate flanges. See illustration below.

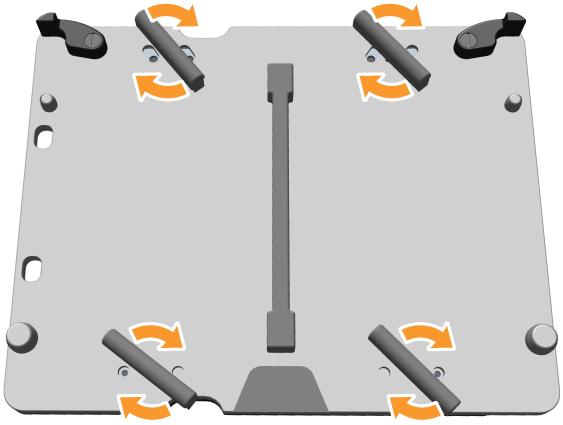


Follow the steps below to switch between low edge and high edge.

Step	Action
1	On the back of the sample tray, use a suitable screwdriver to loosen the screws that hold the four stoppers.



2	Turn the stoppers 180 degrees.



3	Tighten the screws to fasten the stoppers.

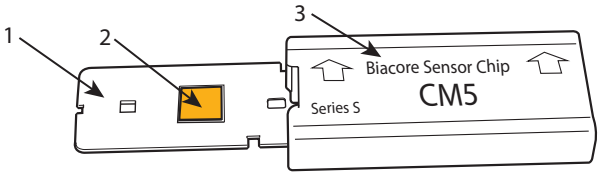
Sample injection

Samples are aspirated from the sample microplates and injected over the surface by the 8 parallel needles in the sample compartment. Switching between sample and running buffer during analysis is controlled by micro-valves in the IFC (see *Integrated microfluidic cartridge (IFC), on page 37*).

3.5 Signal detection and processing

Sensor chip

The sensor chip is a gold-coated glass slide mounted on a supporting frame, enclosed in a protective cassette. Do not remove the sensor chip from the cassette. The illustration below shows the sensor chip separated from the cassette for illustration purposes.



Part	Function
1	Frame
2	Gold-coated glass slide
3	Cassette

Surface plasmon resonance (SPR)

Interactions are monitored through ***surface plasmon resonance (SPR)*** (surface plasmon resonance) in the gold film on the sensor chip surface. SPR occurs under conditions of total internal reflection of incident light on the glass side of the gold film, and leads to a reduction in the intensity of reflected light at a specific combination of wavelength and angle of reflection (the ***SPR angle***). The wavelength is fixed in Biacore systems. The SPR angle is sensitive to the local refractive index of solution very close (within about 150 nm) to the sensor surface on the opposite side of the gold film, so that changes in the SPR angle can be used to monitor the changes in concentration at the sensor surface as interaction proceeds. The light used to generate the signal does not pass through the sample.

SPR response data

The SPR response is monitored continuously in real time by a 2-dimensional detector array that measures the SPR angle for each detection spot. The response is expressed in ***resonance units (resonance units, RU)***. As a rough approximation for proteins on Sensor Chip CM5, 1 RU corresponds to a change in surface concentration of 1 pg/mm^2. This correlation can differ for different molecules and on different sensor chip surfaces.

The raw SPR response is processed and buffered by a microprocessor in the instrument itself, before being transferred to the external computer for display and storage. This configuration means that real-time monitoring continues even when the processing capacity of the external computer is temporarily interrupted. The time resolution of the measurement can be set to 1 or 10 Hz.

3.6 System software

Introduction

The Biacore system includes the Biacore Insight Control Software for controlling the instrument and running experiments, and the separate Biacore Insight Evaluation Software for evaluating the results. The software is provided as a basic package with the essential functionality for running and evaluating experiments, and optional extension packages that offer additional functionality are available. See the *User Manual* for your system for more details.

Connection to the Biacore Insight database is required to use both the control and evaluation software.

Control software

Biacore Insight Control Software is a complete software package for control and supervision of the Biacore 8 series.

The control software is installed on the controlling computer to which the instrument is connected, and is used to control instrument operation. The control software can also be used without a connection to the instrument (or with the instrument switched off) to create analysis methods and open saved results.

Evaluation Software

Biacore Insight Evaluation Software is a stand-alone software for evaluation of results obtained from Biacore 8 series and some other Biacore systems. See the *Biacore Insight Evaluation Software User Manual, (29287248)* for details.

The separate evaluation software is normally installed on the controlling computer to which the instrument is connected, but does not require a connection to the instrument.

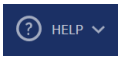
Notifications and reminders

Alerts are shown by a red or orange alert symbol at the top of the screen. Alerts can indicate a requirement for user action or a malfunction. The number in the symbol shows the number of alerts. A red alert symbol indicates an urgent situation.

Click on the symbol and follow the instructions on the screen to act on the alert.

A gray alert symbol indicates a reminder (e.g., a scheduled maintenance operation).

Software help and information

On-screen help is provided with the software. Use the ***Help*** button 

at the top right corner of the screen to get help and access information about the software.

4 Installation

About this chapter

This chapter provides instructions for unpacking, installing, and moving the instrument.

In this chapter

Precautions

WARNING

Heavy package. The delivered instrument package is heavy. Use suitable lifting and moving equipment to handle the package.

WARNING

Heavy object. Use four or more properly trained persons or suitable lifting equipment when moving the instrument. Lifting equipment must not press on the instrument covers. All lifting and moving must be performed in accordance with local regulations.

WARNING

Use only the lifting rods provided with the system to lift the instrument.

WARNING

Personal Protective Equipment (PPE). Whenever packing, unpacking, transporting or moving the system, wear the following:

- Protective footwear, preferably with steel toe-cap.
- Working gloves, protecting against sharp edges.
- Protective glasses.

CAUTION

Make sure that hands or fingers are not trapped under the instrument when the instrument is lifted or moved.

4.1 Site requirements

Introduction

This section describes the requirements for space and supplies in the location where the Biacore 8 series is going to be installed.

The Biacore 8 series must be installed by service personnel from Cytiva, or by other persons authorized by Cytiva.

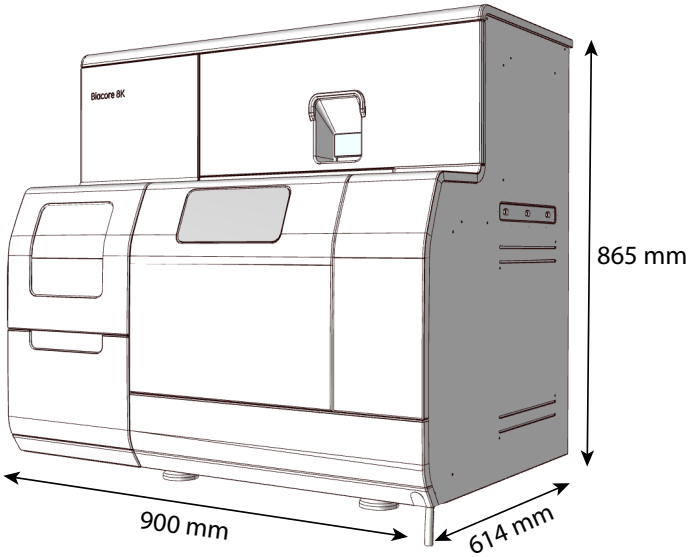
The site requirements checklist in the *Site Preparation Guide* for your instrument (available on the web) must be completed and returned to Cytiva before the system is installed.

Space requirements

The instrument is preferably installed on the trolley provided. Do not install the instrument on a fixed laboratory bench. Access to the back of the instrument is required for service purposes and for lifting the instrument (see *Lift and move on page 53*).

The dimensions of the instrument and trolley are shown in the illustration and table below. There must be at least 10 cm clearance at the back and sides of the instrument to allow adequate air circulation. Place the instrument on the trolley with at least 25 cm space available on the right hand side for buffer and water bottles.

Additional bench space beside the trolley is required for the computer, preferably on the left hand side. The computer keyboard can be placed in the pull-out shelf on the trolley.



Item	Width (mm)	Height (mm)	Depth (mm)	Weight (kg)[1]
Biacore 8K instrument	900	865	614	128
Biacore 8K+ instrument	900	865	614	141
Biacore 8 trolley	1150	850	600	71

[1] Excluding buffer and water bottles and controlling computer.

Environmental conditions

The following general requirements must be fulfilled:

- The room must have exhaust ventilation
- Avoid exposure to direct sunlight
- Dust in the atmosphere must be kept to a minimum

The installation site must comply with the following specifications:

Parameter	Specification
Allowed location	Indoor use only
Ambient temperature Maximum change rate	18°C to 33°C (full performance) 15°C to 35°C (operational) ±0.25°C/min (full performance)
Relative humidity	Up to 31°C: 20% to 80% RH Above 31°C: Maximum humidity decreases linearly to 67% RH at 35°C
Atmospheric pressure	0.85 to 1.15 bar
Altitude	Up to 2000 m
Pollution degree of the intended environment	Pollution degree 2

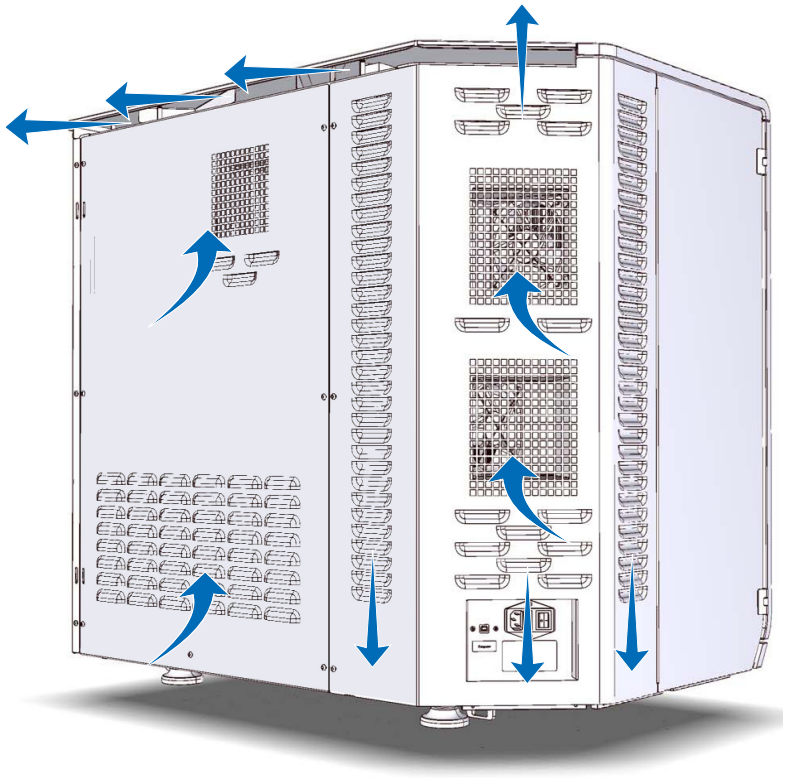
Instrument ventilation

There must be at least 10 cm clearance at the back and sides of the instrument to allow adequate air circulation.

CAUTION

Do not block the air inlet and outlet vents on the back and left side of the instrument.

Main air vents and air flow direction on the instrument are shown in the illustration below.



Electrical power requirements

WARNING

Protective ground. The product must always be connected to a grounded power outlet.

WARNING

Power cord. Use only the power cord delivered with the system. Do not replace the connectors on the power cord.

WARNING

Access to power switch and power cord with plug. Do not block access to the power switch and power cord. The power switch must always be easy to access. The power cord with plug must always be easy to disconnect.

Parameter	Specification
Supply voltage	100 to 240 V~ Maximum ±10% fluctuation from the nominal voltage
Power outlet	Grounded
Frequency	50/60 Hz
Maximum power (excluding controlling computer)	Biacore 8K instrument: 350 VA Biacore 8K+ instrument: 550 VA
Transient overvoltages	Overvoltage category II

4.2 Unpacking, assembly and transport

Precautions

WARNING

Heavy object. Use four or more properly trained persons or suitable lifting equipment when moving the instrument. Lifting equipment must not press on the instrument covers. All lifting and moving must be performed in accordance with local regulations.

WARNING

Use only the lifting rods provided with the system to lift the instrument.

WARNING

Heavy object. The trolley or bench on which the product is installed must have a load capacity of at least 200 kg.

CAUTION

Wear protective shoes with steel toecaps when moving the instrument to protect against falling objects.

CAUTION

Make sure that hands or fingers are not trapped under the instrument when the instrument is lifted or moved.

CAUTION

Lock the wheels on the trolley before using the instrument.

When you receive the delivery

- Record on the receiving documents if there is any apparent damage to the delivery box. Inform your Cytiva representative of any such damage.
- Move the delivery box to a protected location indoors.

Unpacking

The Biacore 8 series must be unpacked and installed by a Cytiva representative.

Check the equipment for any apparent damage. Document any damage carefully and contact your Cytiva representative.

Contact Cytiva if you need to re-pack the instrument for storage or transport.

Assembly

The Biacore 8 series requires no special assembly other than that performed by the Cytiva representative during installation.

Lift and move

The instrument can be moved over a flat floor on the trolley. Unlock the trolley wheels before moving. Remember to lock the wheels again before using the instrument at its new location.

Two lifting rods are supplied with the instrument. Use proper lifting equipment or follow the instructions below if the instrument needs to be lifted from the trolley.

Step	Action
1	Insert the two lifting rods into the fittings under the instrument. The rods must extend sufficiently in front of and behind the instrument so that they can be securely grasped.
2	At least four persons, one at each end of each handle, are required to lift and carry the instrument. ***Note:*** *Observe applicable ergonomic regulations and recommendations when lifting the instrument.*

Transport

To avoid damage, the instrument must be secured before transport over more than limited distances within the laboratory. Contact Cytiva for assistance.

4.3 Computer and software

Computer requirements

Using a computer supplied by Cytiva is recommended. A computer from another supplier must comply with the requirements listed below.

- CPU with at least four cores
- At least 16 GB internal memory
- At least 200 GB free hard disk space
- Screen resolution of at least 1920×1080
- One USB2 port available for instrument connection
- 64-bit Windows 10 Enterprise or 64-bit Windows 10 Professional, English versions.

Note: *The functionality of Biacore Insight software and the Biacore instrument is verified using an English version of Windows. Other languages than English can cause issues.*

Note: *A computer network cable is required (not provided with the instrument).*

eLicense management

Licenses to use the Biacore Insight software are electronic *eLicenses*. Full instructions for downloading and implementing *eLicenses* are given in the *eLicensing Guide for Biacore Systems*.

An eLicense permits a specified number of users to run the Biacore Insight software (including specified software extensions) at any one time. Additional licenses can be obtained from Cytiva for additional concurrent users.

Database installation

Data from the Biacore 8 series (methods, results, run logs, and so on) is stored in a Microsoft® SQL Server database, either locally on the controlling computer or on a network server. SQL server versions 2017 and 2019 are supported. A local database can be installed automatically together with the software. However, a network database is recommended for regular use of the system. A network database is required if data from several instruments is to be stored in the same database. Database installation and management are described in the *Database Installation and Management Guide, (29287249)*.

Note: *A Biacore Insight database can be upgraded to include data from all systems in both the Biacore 1 series and Biacore 8 series. However, all software clients connecting to a common database must use the same software version. This requirement applies for both the Biacore 1 series and Biacore 8 series.*

Download and reinstall software

Biacore Insight Control Software and Biacore Insight Evaluation Software are installed as part of the initial installation procedure.

Follow the steps below if you need to re-install the software for any reason.

Step	Action
1	Download the software from *cytiva.com/eDelivery*. You need to provide your account credentials. Contact Cytiva customer support if you require assistance.
2	Install the software according to the instructions on the download portal.
3	If there is a previous installation of the same version of the software on the computer, choose ***Repair***.

Refer to the separate *Biacore Insight Database Installation and Management Guide* if you need to reinstall the database.

4.4 Connections

Connect to mains power

Follow the steps below to connect the instrument and computer to a mains power source.

WARNING

Power cord. Use only the power cord delivered with the system. Do not replace the connectors on the power cord.

Step	Action
1	Connect the mains power cord delivered with the instrument to the mains power connector on the rear panel (see *Electrical connections, on page 33*). Connect the other end to a mains outlet with protective earth.
2	Make sure that any mains voltage selectors on the computer and peripheral equipment are set correctly.
3	Install the computer and peripheral equipment according to the respective instruction manuals.

Connect the instrument to the computer

NOTICE

Any computer used with the equipment must comply with IEC 60950 or IEC 62368-1 and be installed and used according to the manufacturer's instructions.

NOTICE

The product is designed to be used with liquid supply bottles on the right-hand side of the instrument and the controlling computer on the left. Do not place the computer on the right where there is a risk of spillage.

The computer must be placed on a separate bench on the left-hand side of the instrument.

Connect the supplied USB cable between the USB ports on the computer and the instrument (see *Electrical connections, on page 33*).

NOTICE

When moving the instrument or trolley, disconnect the computer from the instrument to avoid pulling the computer off the bench.

Start the first time

When starting the instrument for the first time after installing the software, perform the steps in the order listed below to make sure that the correct drivers are installed on the controlling computer.

Step	Action
1	Make sure that the software is installed on the computer and that the computer is switched on.
2	Switch on the power to the instrument.
3	Connect the instrument to the computer (see *Connect the instrument to the computer, on page 56*).

5 Operation

About this chapter

This chapter provides the information required to operate the product in a safe way.

In this chapter

Precautions

WARNING

Personal Protective Equipment (PPE). Whenever packing, unpacking, transporting or moving the system, wear the following:

- Protective footwear, preferably with steel toe-cap.
- Working gloves, protecting against sharp edges.
- Protective glasses.

WARNING

Ventilation system. A fume hood or similar ventilation system must be used when working with flammable or noxious substances.

WARNING

Heavy objects. Bottles and waste containers with capacity 5 L or more may be heavy. Take appropriate precautions when lifting.

CAUTION

Do not overload the pull-out shelf on the trolley. The maximum load capacity is marked on the shelf.

CAUTION

The products that are used with toxic or hazardous substances must be marked in accordance with local laws and regulations.

CAUTION

Do not touch the pumps while they are moving.

CAUTION

If buffer and water bottles are placed on a separate bench, make sure that the instrument and bottles are not moved apart during operation.

CAUTION

Ensure that all fluidic tubes are secured and properly connected or sealed at both ends before, during and after operation.

CAUTION

Waste tubes and containers must be secured and sealed to prevent accidental spillage.

CAUTION

Make sure that the waste container has sufficient space for maximum waste volume when the equipment is left unattended.

CAUTION

Frequent use of a computer keyboard and/or mouse may cause repetitive strain injury or disorder. Observe applicable regulations and recommendations for computer workplace ergonomics.

NOTICE

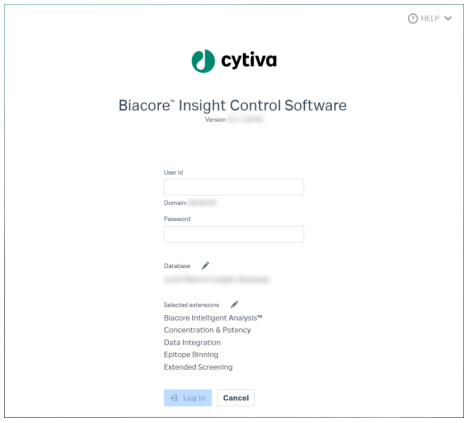
The product is designed to be used with liquid supply bottles on the right-hand side of the instrument and the controlling computer on the left. Do not place the computer on the right where there is a risk of spillage.

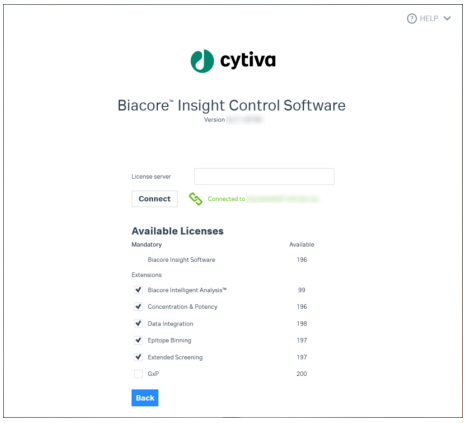
5.1 Starting the system

If the system is switched off

Follow the steps below to start the instrument and Biacore Insight Control Software:

Step	Action
1	Open the lower front panel and close both tube clamps on each of the three peristaltic pumps by pressing the clamps towards the pump body until they click into place (see *Peristaltic pumps on page 35*). Make sure that the clamps stay flush with the pump body on both sides as the clamp is closed.
2	Switch on the power to the instrument (see *Electrical connections, on page 33*).
3	Start the computer.
4	Start Biacore Insight Control Software. *Result:* The login dialog is displayed.



Step	Action
5	Make sure that the correct license server and software extensions are selected. A warning symbol beside the ***Selected extensions*** list, as in the illustration above, indicates that the connection to the license server has not been specified or has been lost. Click the ***Edit*** icon to specify the server details and to select extensions.  Enter the license server name and click ***Connect***. Contact your system administrator if you need assistance. Select the software extensions you wish to use. The number of available licenses for each extension is shown in the dialog. Click ***Close*** when you have entered the details.
6	Click the ***Edit*** icon beside the ***Database name*** to change the selected database. Contact your system administrator if you are uncertain.
7	Enter your account credentials. Your Windows username and password are valid as credentials for the Biacore Insight software. ***Note:*** *Account credentials do not have to be the same for login to Windows and the Biacore Insight software, provided that valid credentials are used in both cases.* ***Note:*** *Biacore Insight software does not support Windows Fast User Switching.*
8	Click ***Log in***.

Step	Action
9	Wait until the instrument self-test is completed and connection to the computer is established as indicated by the instrument number at the top of the screen.

If the system is in standby mode

If the system is in standby mode (the instrument status panel at the bottom of the screen shows ***Running standby flow***), no further action is needed. Standby mode is stopped automatically when a new instrument activity is started.

5.2 Preparing for a run

Set the temperature

Set the flow cell temperature and sample compartment temperature well in advance of starting the run to allow time for the system to equilibrate. Equilibration time for a temperature change of 5°C is about 40 minutes.

Follow the steps below to set the temperature. Repeat the steps for both the flow cell temperature and sample compartment temperature if you need to set both.

Step	Action
1	From the ***Instrument Control*** workspace, add ***Set flow cell temperature*** or ***Set sample compartment temperature*** to the activity queue.
2	Enter the required temperature in the activity workspace.
3	Select ***Set temperature***. Temperature equilibration starts immediately if there are no prior activities in the queue. The current temperature and target temperature are presented in the panel at the bottom of the ***Instrument control*** workspace. ***Note:*** *The **Set ... temperature** activities are executed and removed from the queue quickly. However, temperature equilibration normally takes longer.*

Set up the liquid supply

Follow the instructions below to provide running buffer, distilled water, optional large-volume reagent and waste bottle for the flow system. Required volumes of running buffer and reagent for a run are shown in the ***Instrument control*** workspace. Volumes shown are minimum requirements, calculated from estimated consumption plus a dead volume in the bottle.

Note: *Volumes shown do not include requirements for queued activities that starts automatically or for standby flow following the run. Add the appropriate volumes of buffer, reagent and water to those shown in the workspace (see Standby mode on page 69 for volumes required during standby).*

Step	Action
1	Fill a bottle with distilled water and place it on the right-hand side of the instrument. Insert the tube marked **WATER**.

Step	Action
2	Fill up to 4 bottles with running buffer(s) as required and place them on the right-hand side of the instrument. Insert the buffer inlet tubes according to the buffer requirements for the run. Configuration of the buffer selector is described in the *User Manual*. ***Note:*** *Biacore 8K systems with Product No. 29146489 do not support buffer selector functions and only have one buffer tube.* ***Note:*** *For Biacore 8K Prod. No. 29327020 and Biacore 8K+, the* **BUFFER A** *tube must always be placed in buffer, even when another buffer is used as running buffer. Other unused buffer tubes must be capped or placed in water or buffer.*
3	If required, prepare a bottle with large-volume reagent and place it on the right-hand side of the instrument. Insert the tube marked **REAGENT**. If a large-volume reagent is not used, insert the **REAGENT** tube into the water bottle.
4	Make sure that all liquid supply tubes are securely placed at the bottom of the liquid.
5	Place the waste container on the trolley shelf under the instrument. Insert the waste tube. ***Note:*** *There must always be free passage in the waste tube to prevent flooding of the instrument. Make sure that the tube is not kinked.*

Insert a sensor chip

If the instrument is in standby mode, a sensor chip is docked in the instrument. Normally, you need to replace this sensor chip with one appropriate for your run. Follow the steps below to change the sensor chip. Follow the same steps but omit step 2 if the instrument has been restarted from shutdown.

Step	Action
1	Add ***Change chip*** to the activity queue.
2	If a sensor chip is already docked in the instrument, click ***Undock chip*** and remove the chip from the sensor chip port.
3	Select ***New chip*** and enter the details of the sensor chip for the run. Alternatively, select ***Existing chip*** and choose a chip from the list.
4	Insert the sensor chip and close the chip door.

Step	Action
5	Click ***Dock chip***. ***Note:*** *If you click **Dock chip** before closing the chip door, a notification is issued. Close the door and select **Retry** in the notification.*

Note: *For runs requiring highest performance, allow the flow system to equilibrate in standby mode at least overnight after changing the sensor chip or changing solutions. Extend the equilibration time to at least 24 h if the detergent concentration in the running buffer is changed.*

Select or create a method

Follow the instructions below to set up the method for the run. See the *User Manual* for more details.

Step	Action
1	Go to the ***Methods*** workspace in the control software.
2	Open a predefined or existing method from the database. Make any modifications that can be required to the method definition.
3	Go to the ***Variables and positioning*** tab. Enter or modify the variable details as required including sample information, microplate types and position assignments.
4	(Optional) Go to the ***Cycle overview*** tab and check that the run is set up correctly. If you need to make any adjustments, return to the ***Method Definition*** tab and adjust the necessary settings.
5	(Optional) Print the ***Plate layout*** information as an aid in preparing microplates.

5.3 Preparing and loading samples

Prepare samples and reagents

Follow the steps below to prepare samples and reagents in a microplate.

Step	Action
1	Dispense the samples and reagents into the microplate wells according to the ***Plate layout*** information in the method. Make sure that there are no air bubbles trapped at the bottom of the microplate wells. It is particularly easy to trap air bubbles in 384-well microplates. Use of a microplate centrifuge to remove air bubbles is recommended. ***Note:*** *Buffer is injected over any channels that are not used. You need to add buffer to the appropriate wells on the microplate(s).*
2	Cover the microplates as recommended (see *Microplate covers on page 41*) to prevent evaporation from the samples during analysis. ***Note:*** *Microplate foils and septa can cover the well position identifiers on the microplates. It is recommended to mark the* **A1** *corner of the microplate after attaching the foil or septum. Take care not to mark the foil or septum directly over a well position.*

Mount the microplate on a sample tray

Follow the steps below to mount the microplate on the sample tray.

Step	Action
1	Open the catch on the sample tray and place the microplate on the tray with position **A1** at the front left, as marked on the tray (see *Sample trays on page 41*).
2	Close the catch and make sure that the microplate is properly seated on the tray (see *Sample trays on page 41*).

5.4 Performing the run

Start the run

Follow the instructions below to start the run in the software.

Step	Action
1	Click ***Send to queue*** in the method workspace. *Result:* The method is added to the activity queue.
2	Select the running buffer for the method. ***Note:*** *The* **BUFFER** *tube (Biacore 8K Prod. No. 29146489) or* **BUFFER A** *tube (Biacore 8K Prod. No. 29327020 and Biacore 8K+) must always be placed in buffer, even when another buffer is used as running buffer. Any other unused buffer tubes must be capped or placed in water or buffer.*
3	Assign the tray(s) to sample hotel positions.
4	If the sample hotel door is closed, select ***Open*** from the instrument status pane in the control software.
5	Open the hotel door fully (see *Sample hotel door on page 31*).
6	Place the sample tray(s) on the correct shelf in the sample hotel as assigned in the software.
7	Close the hotel door. Make sure that the status is shown as ***Closed*** in the software.
8	Click ***Ready to start***.
9	Navigate to the required folder and provide a name for the run. Click ***Save***. *Result:* The run starts as soon as all previously queued activities are complete. Actual run start can be delayed if the flow cell temperature is not stable (see *Flow cell temperature on page 40*).

You can load the sample tray(s) into the sample hotel at any time except when a tray is being moved between the hotel and the sample compartment. If a sample tray is not present in the hotel when required by the method, a notification is issued and the run does not continue until the tray is provided.

NOTICE

The system checks that a sample tray is present in the hotel, but does not detect the presence or size of the microplate(s) on the tray. It is the user's responsibility to make sure that microplates corresponding to the software settings are mounted on the tray. Using incorrect microplates can damage the injection needles.

Monitor the run

Sensorgrams generated as the run progresses are displayed in the ***Instrument control*** workspace (see the *User Manual* for details).

At the end of the run, the next activity in the queue starts automatically unless user input is required. Otherwise, the instrument is automatically placed in standby mode.

Clean-up after the run

The following activities must be performed as required after a run:

- Remove any microplates from the sample hotel.
- Empty the reagent bottle and replace with water or buffer.
- Make sure there is sufficient liquid for the intended standby period.
- Empty the waste bottle.
- Clean the drip tray if necessary.

Standby mode

Always leave the system in standby mode unless the instrument is to be shut down. Standby mode uses the current buffer tube.

Tip: *The current buffer tube is highlighted in blue in the status bar in the control software.*

Standby mode maintains a continuous low flow of liquid through the flow system. Recommended liquids for standby operation over longer periods are buffer for the **BUFFER** supply tubing and water for **WATER** and **REAGENT** tubing. Liquid from the **BUFFER** inlet, but not from **WATER** or **REAGENT**, passes over the sensor surface during standby.

A sensor chip is required in the instrument during standby operation.

The maximum unattended standby period is 7 days. Select ***Restart*** on the instrument status pane to extend the standby period by resetting the timer to 7 days. Make sure there is sufficient liquid supplied to each inlet for the intended standby period. Approximate liquid consumption for each inlet tubing is listed below:

Tubing	Consumption (mL/24 h)	Passes over sensor surface
BUFFER	250	Yes
WATER [1]	150	No
REAGENT [1]	25	No

[1] Place both the **REAGENT** and **WATER** tubing in the water bottle.

5.5 Closing down the software

The options available when the control software is shut down depend on the current state of the instrument and the activity queue, as described in the following table.

State	Options
No instrument activity	1. Start standby and close the software (recommended)[1]. 2. Close the software.
Standby running	Close the software.
Activity queue not empty, but no activity started	Close the software. Activities in the queue are discarded.
Activity running or pending	The software cannot be closed until the activity is completed or aborted.

[1] Standby continues to run for up to 7 days after the software is closed.

6 Maintenance

About this chapter

This chapter describes maintenance and service procedures that can be performed by the user.

In this chapter

Precautions

WARNING

Explosion hazard. Do not run any maintenance procedures that use 20% ethanol at sample compartment temperatures above 25°C.

WARNING

Always wear appropriate protective clothing and equipment during operation and maintenance of the product. Use required safety equipment when handling hazardous substances.

WARNING

All service and repairs, with the exception of operations explicitly described in the user documentation, must be carried out by personnel authorized by Cytiva. Do not open any covers or replace any parts unless specifically stated in the user documentation.

WARNING

Concentrated disinfectant solutions are corrosive. Use appropriate personal protective equipment when handling such solutions.

WARNING

Liquids in the buffer bottles or tubing may be toxic or flammable or may cause chemical burns or irritation to skin and eyes. Take appropriate precautions in the event of bottle breakage, accidental spillage and insecure fitting of tubings to bottles.

WARNING

Decontaminate the instrument before performing maintenance on any instrument parts. Contact your local service representative for further information about decontamination procedures.

WARNING

Do not use more than 250 mL 20% ethanol on any single occasion for maintenance procedures.

6.1 Cleaning before planned service

Cleaning before planned maintenance/service

To ensure the protection and safety of service personnel, all equipment and work areas must be clean and free of any hazardous contaminants before a Service Engineer starts maintenance work.

Please complete the checklist in the *On Site Service Health and Safety Declaration Form* or the *Health and Safety Declaration Form for Product Return or Servicing*, depending on whether the instrument is going to be serviced on site or returned for service, respectively.

Health and safety declaration forms

Health and safety declaration forms are available for copying or printing in the *Reference information* chapter of this manual, or on digital media supplied with the user documentation.

6.2 User maintenance operations

Introduction

Regular maintenance is important for continued high performance of the system. This section describes the maintenance operations that must be performed by the user. More extensive maintenance must be performed on a regular basis by a Cytiva service representative.

Maintenance schedule

Perform user maintenance operations at regular intervals according to the table below.

Interval	Action
Daily/after each run	Empty the waste bottle.
Weekly	Clean the flow system (***Desorb***).
Monthly	Clean the instrument cover.
	Clean and disinfect the flow system (***Desorb and sanitize***).
	Check system performance (***System check***).

A reminder notification is issued in the top banner of the control software when scheduled maintenance is due. Click the notification symbol for information including options to add the maintenance operation to the activity queue or ignore the reminder.

Required materials

Materials required for user maintenance are summarized in the table below.

Maintenance operation	Solution/item
Cleaning the flow system	BIAdesorb solutions 1 and 2
	Series S Sensor Chip Maintenance or a used sensor chip
Disinfecting the flow system	Disinfectant solution (see *Clean and disinfect the flow system* for recommendations)
Normalizing the detector	BIAnormalizing solution (70%)
System performance check	Biacore test solution
	HBS-EP+ buffer
	Unused Series S Sensor Chip CM5

In addition, distilled water and clean, lint-free wipes can be required.

Clean the instrument

WARNING

Liquids in the buffer bottles or tubing may be toxic or flammable or may cause chemical burns or irritation to skin and eyes. Take appropriate precautions in the event of bottle breakage, accidental spillage and insecure fitting of tubings to bottles.

When required, clean the outside of the instrument with a soft cloth or tissue, moistened with water or mild detergent.

If necessary, clean the caps on the waste and liquid supply bottles as follows:

Step	Action
1	Unscrew the cap from the bottle.
2	Loosen the tube fittings and remove the tubes from the cap.
3	Rinse the cap in deionized water.
4	Re-attach the tubes to the cap and tighten the fittings firmly.

Clean the sample hotel

To clean the sample hotel, remove all sample trays and wipe the hotel surfaces with a moistened cloth or tissue. If cleaning is required in inaccessible places, contact Cytiva for assistance.

Clean and disinfect the flow system

WARNING

Concentrated disinfectant solutions are corrosive. Use appropriate personal protective equipment when handling such solutions.

Run the ***Desorb*** tool from the ***Instrument control*** workspace and follow the instructions on the screen to clean the flow system. You need vials in a reagent rack for BIAdesorb 1 and BIAdesorb 2 solutions.

To prevent bacterial growth in the system, run the ***Desorb and sanitize*** tool. You need bottles or centrifuge tubes for BIAdesorb 1 and BIAdesorb 2 solutions (minimum 250 mL each) and one bottle for disinfectant solution (minimum 350 mL), which can be placed in accessory holders attached to the holder rail. All supply tubes are placed in the same bottle and are moved between the bottles during the procedure. Sodium

hypochlorite (0.6% to 1.0% active chlorine) is recommended as disinfectant solution. Instructions for preparing this solution from commercial sodium hypochlorite solutions are given in the *Instructions for Use* for the *Biacore Maintenance Kit, type 3*. Do not use hydrogen peroxide-based disinfectants or other products that release gases on use.

The system must be allowed to run buffer in standby mode for at least 3 to 4 hours after the ***Desorb and sanitize*** tool.

Clean spills in the sample compartment

When runs are performed at temperatures below ambient, condensation can occur in the sample compartment. Condensed water can run on to the drip tray underneath the instrument and normally evaporates from there. In humid atmospheres with a large temperature difference between ambient and sample compartment, remove and empty the drip tray if necessary.

In the event of malfunction that causes spillage of buffer or reagent in the sample compartment (e.g., blockage in the connection block or leakage from a liquid supply tube), contact your Cytiva service representative.

Normalize the detector

Normalizing the detector adjusts the detector response to compensate for small variations in the optical system that can arise when sensor chips are docked and undocked. Normalization is recommended to be performed periodically, for example once a month, as a test of the system and to fine tune the detector responses. The ***Normalize*** tool must also be used after chip exchange as an extra precaution if best possible performance is required. The procedure can be run either before a ligand has been attached or before the first analysis run using the immobilized chip.

The procedure injects BIAnormalizing solution (70%) over the chip surface.

Replace mains fuses

WARNING

Disconnect power. Always disconnect power from the instrument before replacing fuses.

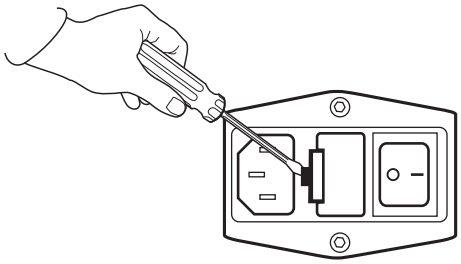
WARNING

For continued protection from fire hazard, replace only with same type and rating of fuse.

CAUTION

Do not replace the mains fuses if you suspect that there may be a malfunction in the instrument. Contact your Cytiva service representative for advice.

Follow the instructions below to replace the mains fuses.

Step	Action
1	Turn off the power to the instrument.
2	Disconnect the mains cord from the mains power inlet.
3	Insert a small flat-bladed screwdriver under the tab on the fuse drawer cover.
	
4	Prise open the fuse drawer cover.
5	Replace both fuses. See the instrument product label for fuse ratings.
6	Close the fuse drawer cover and reconnect the mains supply.

6.3 Storage

Introduction

This section describes the conditions under which the instrument should be stored for long periods (several months or more).

Storage conditions

If the instrument is to be put into storage, first perform the ***Shutdown*** procedure to empty and dry the flow system, then clean the outside surfaces of the instrument using a soft cloth and water or a mild detergent. Release the peristaltic pump clamps before storage (see *Peristaltic pumps on page 35*).

Maintain normal conditions of temperature and humidity while the system is in storage:

- Temperature: preferably room temperature, not below freezing
- Relative humidity: non-condensing, preferably low humidity

Contact Cytiva if you are uncertain of storage conditions.

7 Troubleshooting

About this chapter

This chapter describes troubleshooting procedures.

In this chapter

7.1 Troubleshooting tools

Notifications

Malfunctions and other unexpected situations are indicated by a notification at the top of the screen (see *Notifications and reminders on page 45*). In general, the notification provides brief instructions for corrective actions if the situation can be corrected by the user.

System check

The ***System check*** tool in the ***Instrument control*** workspace performs a comprehensive check of system performance, using Biacore test solution and an unused Series S Sensor Chip CM5.

Follow the instructions below to run ***System check***.

NOTICE

Use only the solutions and sensor chip specified in the ***System check*** instructions. The results may not be correct if any other materials are used.

Step	Action
1	Set the flow cell and sample compartment temperature to 25°C.
2	Fill the buffer bottle with HBS-EP+ buffer. For the Biacore 8K systems with Product No. 29327020 and Biacore 8K+ systems, place the **BUFFER A** and **BUFFER C** tubes in the buffer bottle, and the **BUFFER B** and **BUFFER D** tubes in deionized water. For the Biacore 8K systems with Product No. 29146489, place the **BUFFER** tube in the buffer bottle.
3	Dock an unused Series S Sensor Chip CM5. The sensor surface is not affected by the ***System check*** procedure.
4	Add ***System check*** to the activity queue. Read the instructions on the screen, then choose ***Next***.
5	Prepare a standard 96-well microplate with HBS-EP+ buffer and Biacore test solution according to the ***Positioning*** information. ***Note:*** *You can change the sample positioning if desired. The microplate type is fixed.*
6	Choose ***Start run*** and provide a location and name for the result file.

System check results

The results of ***System check*** are stored in the database and can be opened in the ***Runs*** workspace. The table below provides guidelines for interpreting the results.

Test	Failure	Possible cause/Action
Liquid supply block	Air in injection	The clamp on one or more peristaltic pump is not closed.
		Tubing constricted or not fully inserted into buffer or water.
	Deviates from acceptance criteria	Inlet tubes in wrong bottle.
		Deposits in the liquid supply block. Run ***Change solution*** three times and rerun ***System check***.
Injections	Failed rise/fall time	Air in flow system due to incomplete solution change. Run ***Change solution*** and rerun ***System check***.
		Air in flow system due to leakage or blocked channel. Contact Cytiva service.
	Air in injection	Insufficient sample volume.
	Failed leakage	Particles on the sensor chip. Change the chip and rerun ***System check***.
		IFC or pneumatic system failure. Contact Cytiva service.
Mixing	Air in injection	Insufficient sample volume.
	Flow system leakage	Contact Cytiva service.
Refracto-meter	Too low values	A new chip was not used.
	Too high or too low values	Incorrect test solution or buffer.
Noise	Noisy	Make sure that the instrument is not exposed to vibration sources such as centrifuges.
	Drifting baseline	A new chip was not used.
		Temperature not stable.

7.2 Instrument problems

Introduction

This section lists potential instrument problems that can be addressed by the user. If problems arise that are not described in this section, contact Cytiva.

Problems and solutions

The table below summarizes problems and corrective actions. For problems not listed here or explained in an on-screen notification, contact your Cytiva service representative.

Symptom	Possible cause	Corrective action
No connection to instrument.	USB malfunction.	Disconnect and reconnect USB cable. Power off and restart complete system, including computer.
Cannot open sample hotel door.	The door release is inactivated while trays are being moved between the hotel and the sample compartment.	This is normal. Wait until the tray movement is complete.
	Power failure.	Restore power. See *Recover samples when the power has failed on page 24* if you need to recover the microplates following a power failure.
Cannot close sample hotel door.	Sample tray not correctly mounted.	Check that the locking levers on the sample tray are properly closed, then remount the tray.
Cannot remove sensor chip.	Instrument malfunction.	Contact Cytiva service.
Sensor chip port does not open.	Instrument malfunction.	Contact Cytiva service.
Liquid appears on the trolley beneath the instrument.	High ambient humidity together with low sample compartment temperature (excessive condensation).	Empty the drip tray. Keep the sample hotel closed as much as possible.

Symptom	Possible cause	Corrective action
	Liquid supply overflow in the sample compartment.	Clean the spillage. Check that all peristaltic pump clamps are correctly closed. Contact Cytiva service if the problem persists.
Error alert indicating problem with sample handler movement.	Needle collision with microplate due to use of incorrect microplate type.	Inspect the needles through the sample compartment window. If they are undamaged and not displaced, the instrument can be used. Otherwise contact Cytiva service.
Injections repeatedly missing in one or more channels.	Channel blockage.	Run ***Change solutions*** several times. Contact Cytiva service if the problem persists.
Baseline disturbances before or after injection.	Some disturbances from injection preparation and wash are normal. Baseline disturbances are more noticeable at higher flow cell temperatures and higher flow rates.	Contact Cytiva service if the disturbances are excessive.
Signal disturbances during dissociation phase.	Some disturbance from pump fill operations is normal. Disturbances are more noticeable at higher flow cell temperatures and higher flow rates.	Check the ***Event log*** in the ***Runs*** workspace to locate pump fill operations. Contact Cytiva service if the disturbances are excessive.
	Air bubbles formed in samples in the flow cell.	Set the sample compartment temperature the same as or close to the flow cell temperature.
	Mechanical disturbance.	Close the sample hotel door gently if it is opened during a run.
		Avoid bumping the instrument or trolley.

Symptom	Possible cause	Corrective action
Baseline drift.	Flow system not equilibrated with buffer, particularly when buffer includes detergent.	For highest sensitivity, allow the flow system to equilibrate at least overnight after changing buffer (24 h if the detergent concentration is changed).
	Sensor chip not equilibrated with buffer.	For highest sensitivity, allow the system to stabilize for a few hours after docking a new sensor chip and immobilizing ligand.
		Always include at least one startup cycle at the beginning of the run. For best performance, use 3 to 5 startup cycles.
Unexpected response or sudden response shifts during injection.	Air precipitation in the injected solution (injection of air in one channel can also affect adjacent channels). The risk is highest at elevated flow cell temperatures and low sample compartment temperatures, and when the injection time is a large part of the total cycle time.	Make sure that all microplate wells and liquid supply bottles contain sufficient liquid. Make sure that there are no air bubbles in microplate wells. Use of a microplate centrifuge is recommended, particularly for 384-well microplates. If samples do not have to be kept cold, set the sample compartment temperature to the same as, or close to, the flow cell temperature. Increase dissociation times so that injections form a smaller part of the total cycle time. Keep cycle times shorter than 10 minutes if possible.
Response out of range at the end of injection.	Insufficient sample volume.	Make sure that sample volumes correspond with the recommendations in the software.

Symptom	Possible cause	Corrective action
Unexpectedly high bulk response in samples.	Sample evaporation before or during run.	Cover the microplates as soon as possible after preparation. Position the microplate cover carefully over the wells. Do not store covered microplates for longer than one working day. ***Note:*** *Some buffer additives, particularly DMSO, give high bulk responses.*
Baseline response out of range.	Buffer supply is insufficient.	Make sure there is sufficient buffer in the buffer bottle, and that the buffer supply tube is at the bottom of the bottle.
Sudden response shifts during dissociation or baseline at elevated flow cell temperatures.	Inadequate buffer degassing.	Contact Cytiva service.
Recurrent signal spikes during injection and dissociation phase.	IFC malfunction.	Contact Cytiva service.
Sensorgram oscillation during injections.	Incomplete needle wash.	Check that all peristaltic pump clamps are correctly closed.
	Carry-over from needle.	Cover microplates with septa if repeated injections are performed from the same well (i.e., samples are pooled). Do not use foil for microplates with pooled samples.
	Microplate wells overfilled so that vent holes in the microplate septa are blocked by liquid.	Use recommended sample volumes. Do not overfill wells.

Symptom	Possible cause	Corrective action
	Organic wash or regeneration solutions (e.g., ethylene glycol, isopropyl alcohol) incompletely washed out of the system.	Minimize the injection time for alcohols and similar solvents. Increase the dissociation time or include a ***Wait*** or buffer ***Wash*** after injecting alcohols and similar solvents.
Delayed injection start.	Air in flow system.	Run ***Change solutions***.
	Leakage.	Contact Cytiva service.
	Injection from empty microplate well. Injection of air can delay subsequent injections in the same channel.	Make sure all used microplate positions contain sufficient liquid.

8 Reference information

About this chapter

This chapter provides technical specifications for the Biacore 8 series, chemical resistance, recycling, and regulatory information.

In this chapter

8.1 System specifications

General specifications

Parameter	Specification
Dimensions (W × H × D) Instrument Trolley	 900 × 865 × 614 mm 1150 × 850 × 600 mm
Net weight Biacore 8K instrument Biacore 8K+ instrument Trolley	 128 kg 141 kg 71 kg
Power supply	100 to 240 V~ 50/60 Hz Maximum ±10% fluctuation from the nominal voltage
Maximum power consumption (excluding computer) Biacore 8K instrument Biacore 8K+ instrument	 350 VA 550 VA
Fuse rating	2 × (T6.3 AH 250V)
Overvoltage category	II
Analysis temperature	4°C to 40°C. Maximum 18°C below ambient.
Tray temperature	4°C to 40°C. Maximum 18°C below ambient.
Acoustic noise level	<70 dB(A)

Environment

Parameter	Specification
Allowed location	Indoor use only
Ambient temperature (operation) Maximum change rate	18°C to 33°C (full performance) 15°C to 35°C (operational) ±0.25°C/min (full performance)
Ambient temperature (transportation) Maximum change rate	-25°C to 60°C ±1°C/min.
Relative humidity (operation)	Up to 31°C: 20% to 80% RH Above 31°C: Maximum humidity decreases linearly to 67% RH at 35°C
Relative humidity (transportation)	5% to 95%
Atmospheric pressure (transportation)	0.85 to 1.15 bar
Altitude (operation)	Up to 2000 m
Pollution degree of the intended environment	Pollution degree 2

Operational

Parameter	Specification
Sample capacity Biacore 8K Biacore 8K+	 Up to four microplates (96- or 384-well) per run Up to 12 microplates (96- or 384-well) per run
Sensor chip format	Sensor Chip Series S (Cytiva)

8.2 Chemical resistance of wetted parts

Introduction

This section gives some general guidelines concerning chemical resistance for the Biacore 8 series flow system.

The flow system and sensor chip are the only wetted parts of the Biacore 8 series. In most analysis situations, the chemical resistance of the system as a whole is limited by the properties of the sensor surface and the attached ligand. See the respective Instructions for Use for guidelines relating to the sensor chip.

In general, the flow system components withstand long-term exposure to common aqueous buffer solutions used in biochemical analyses. The table below lists compatibility with other common substances. Contact your Cytiva representative for recommendations concerning substances not listed here.

Chemical resistance

Concentrated organic solvents as well as long-term exposure to extremes of pH (<3 and >11) must be avoided. For solutions with short-term compatibility, do not use as running buffer or for injections longer than 1 minute.

Solution	Concentration	Compatibility
Acetonitrile	50%	Short term
Dimethyl sulfoxide (DMSO)	10% 50%	Long term Short term
Ethanol	10% 20%	Long term Short term
Ethylene glycol	100%	Short term
Glycerol	25% 70%	Long term Short term
Guanidine-HCl	6 M	Short term
Hydrochloric acid	100 mM	Short term
Imidazole	300 mM	Short term
Isopropanol	20%	Short term
Isopropanol/NaOH mixture	20%/30 mM	Short term
Magnesium chloride	4 M	Short term
Sodium chloride	1 M 5 M	Long term Short term

Solution	Concentration	Compatibility
Sodium hydroxide	250 mM	Short term
Urea	8 M	Short term

8.3 Recycling information

Introduction

This section contains information about the decommissioning of the product.

CAUTION

Always use appropriate personal protective equipment when decommissioning the equipment.

Decontamination

The product must be decontaminated before decommissioning. All local regulations must be followed with regard to scrapping of the equipment.

Disposal of the product

When taking the product out of service, the different materials must be separated and recycled according to national and local environmental regulations.

Recycling of hazardous substances

The product contains hazardous substances. Detailed information is available from your Cytiva representative.

Disposal of electrical components

Waste electrical and electronic equipment must not be disposed of as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of the equipment.

8.4 Regulatory information

Introduction

This section lists the directives and standards that apply to the Biacore 8 series.

In this section

8.4.1 Contact information

Contact information for support

To find local contact information for support and sending troubleshooting reports, visit *cytiva.com/contact*.

Manufacturing information

The table below summarizes the required manufacturing information.

Requirement	Information
Name and address of manufacturer	Cytiva Sweden AB Björkgatan 30 SE 751 84 Uppsala Sweden
Telephone number of manufacturer	+ 46 771 400 600

8.4.2 European Union and European Economic Area

Introduction

This section describes regulatory information for the European Union and European Economic Area that applies to the equipment.

Conformity with EU Directives

See the EU Declaration of Conformity for the directives and regulations that apply for the CE marking.

If not included with the product, a copy of the EU Declaration of Conformity is available on request.

CE marking

The CE marking and the corresponding EU Declaration of Conformity is valid for the instrument when it is:

- used according to the *Operating Instructions* or user manuals, and
- used in the same state as it was delivered, except for alterations described in the *Operating Instructions* or user manuals.

Regulatory compliance of connected equipment

Any electrical equipment connected to the Biacore 8 series shall meet the safety requirements of EN/IEC 61010-1, or other relevant national safety regulations and standards. Within EU, connected equipment must be CE marked.

8.4.3 Great Britain

Introduction

This section describes regulatory information for Great Britain that applies to the equipment.

Conformity with UK Regulations

See the UK Declaration of Conformity for the regulations that apply for the UKCA marking.

If not included with the product, a copy of the UK Declaration of Conformity is available on request.

UKCA marking

The UKCA marking and the corresponding UK Declaration of Conformity is valid for the instrument when it is:

- used according to the *Operating Instructions* or user manuals, and
- used in the same state as it was delivered, except for alterations described in the *Operating Instructions* or user manuals.

8.4.4 Eurasian Economic Union (Евразийский экономический союз)

This section describes the information that applies to the product in the Eurasian Economic Union (the Russian Federation, the Republic of Armenia, the Republic of Belarus, the Republic of Kazakhstan, and the Kyrgyz Republic).

Introduction

This section provides information in accordance with the requirements of the Technical Regulations of the Customs Union and (or) the Eurasian Economic Union.

Введение

В данном разделе приведена информация согласно требованиям Технических регламентов Таможенного союза и (или) Евразийского экономического союза.

Manufacturer and importer information

The following table provides summary information about the manufacturer and importer, in accordance with the requirements of the Technical Regulations of the Customs Union and (or) the Eurasian Economic Union.

Requirement	Information
Name, address and telephone number of manufacturer	See *Manufacturing information*
Importer and/or company for obtaining information about importer	Cytiva RUS LLC 109004, Moscow internal city area Tagansky municipal district Stanislavsky str., 21, building 5, premises I, offices 24,25,29 Russian Federation Telephone: +7 985 192 75 37 E-mail: *rucis@cytiva.com*

Информация о производителе и импортере

В следующей таблице приводится сводная информация о производителе и импортере, согласно требованиям Технических регламентов Таможенного союза и (или) Евразийского экономического союза.

Требование	Информация
Наименование, адрес и номер телефона производителя	См. *Информацию об изготовлении*
Импортер и/или лицо для получения информации об импортере	ООО "Цитива РУС" 109004, г. Москва вн. тер. г. муниципальный округ Таганский ул. Станиславского, д. 21 стр. 5, помещ. I, ком. 24,25,29 Российская Федерация Телефон: +7 985 192 75 37 Адрес электронной почты: *rucis@cytiva.com*

Description of symbol on the system label
Описание обозначения на этикетке системы

This Eurasian compliance mark indicates that the product is approved for use on the markets of the Member States of the Customs Union of the Eurasian Economic Union

Данный знак о Евразийском соответствии указывает, что изделие одобрено для использования на рынках государств-членов Таможенного союза Евразийского экономического союза

8.4.5 Regulations for North America

Introduction

This section describes the information that applies to the product in the USA and Canada.

FCC compliance

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Note: *The user is cautioned that any changes or modifications not expressly approved by Cytiva could void the user's authority to operate the equipment.*

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

8.4.6 Regulatory statements

Introduction

This section shows regulatory statements that apply to regional requirements.

EMC emission, CISPR 11: Group 1, Class A statement

NOTICE

This equipment is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments.

South Korea

Regulatory information to comply with the Korean technical regulations.

NOTICE

Class A equipment (equipment for business use).

This equipment has been evaluated for its suitability for use in a business environment.

When used in a residential environment, there is a concern of radio interference.

유의사항

A급 기기 (업무용 방송통신 기자재)

이 기기는 업무용환경에서 사용할 목적으로 적합성평가를 받은 기기

로서 가정용 환경에서 사용하는 경우 전파간섭의 우려가 있습니다.

8.4.7 Declaration of Hazardous Substances (DoHS)

This section describes the information that applies to the product in China.

根据 SJ/T11364-2014《电子电气产品有害物质限制使用标识要求》特提供如下有关污染控制方面的信息。

The following product pollution control information is provided according to SJ/T11364-2014 Marking for Restriction of Hazardous Substances caused by electrical and electronic products.

电子信息产品污染控制标志说明
Explanation of Pollution Control Label

该标志表明本产品含有超过中国标准 GB/T 26572《电子电气产品中限用物质的限量要求》中限量的有害物质。标志中的数字为本产品的环保使用期，表明本产品在正常使用的条件下，有毒有害物质不会发生外泄或突变，用户使用本产品不会对环境造成严重污染或对其人身、财产造成严重损害的期限。单位为年。

为保证所申明的环保使用期限，应按产品手册中所规定的环境条件和方法进行正常使用，并严格遵守产品维修手册中规定的定期维修和保养要求。

产品中的消耗件和某些零部件可能有其单独的环保使用期限标志，并且其环保使用期限有可能比整个产品本身的环保使用期限短。应到期按产品维修程序更换那些消耗件和零部件，以保证所申明的整个产品的环保使用期限。

本产品在使用寿命结束时不可作为普通生活垃圾处理，应被单独收集妥善处理。

This symbol indicates the product contains hazardous materials in excess of the limits established by the Chinese standard GB/T 26572 Requirements of concentration limits for certain restricted substances in electrical and electronic products. The number in the symbol is the Environment-friendly Use Period (EFUP), which indicates the period during which the hazardous substances contained in electrical and electronic products will not leak or mutate under normal operating conditions so that the use of such electrical and electronic products will not result in any severe environmental pollution, any bodily injury or damage to any assets. The unit of the period is “Year”.

In order to maintain the declared EFUP, the product shall be operated normally according to the instructions and environmental conditions as defined in the product manual, and periodic maintenance schedules specified in Product Maintenance Procedures shall be followed strictly.

Consumables or certain parts may have their own label with an EFUP value less than the product. Periodic replacement of those consumables or parts to maintain the declared EFUP shall be done in accordance with the Product Maintenance Procedures.

This product must not be disposed of as unsorted municipal waste, and must be collected separately and handled properly after decommissioning.

有害物质的名称及含量
Name and Concentration of Hazardous Substances

产品中有害物质的名称及含量
Table of Hazardous Substances' Name and Concentration

部件名称 Compo-nent name	有害物质 Hazardous substance					
	铅 (Pb)	汞 (Hg)	镉 (Cd)	六价铬 (Cr(VI))	多溴联苯 (PBB)	多溴二苯醚 (PBDE)
29327020 Biacore 8K	X	0	0	0	0	0
29283382 Biacore 8K+	X	0	0	0	0	0

0: 表示该有害物质在该部件所有均质材料中的含量均在 GB/T 26572 规定的限量要求以下。

X: 表示该有害物质至少在该部件的某一均质材料中的含量超出 GB/T 26572 规定的限量要求。

- 此表所列数据为发布时所能获得的最佳信息.

0: Indicates that this hazardous substance contained in all of the homogeneous materials for this part is below the limit requirement in GB/T 26572.

X: Indicates that this hazardous substance contained in at least one of the homogeneous materials used for this part is above the limit requirement in GB/T 26572

- Data listed in the table represents best information available at the time of publication.

8.5 Ordering information

Ordering information for the Biacore 8 series and related products can be found on *cytiva.com/biacore*.

8.6 Health and Safety Declaration Form

On site service

cytiva

On Site Service Health & Safety Declaration Form

Service Ticket #:	

To make the mutual protection and safety of Cytiva service personnel and our customers, all equipment and work areas must be clean and free of any hazardous contaminants before a Service Engineer starts a repair. To avoid delays in the servicing of your equipment, complete this checklist and present it to the Service Engineer upon arrival. Equipment and/or work areas not sufficiently cleaned, accessible and safe for an engineer may lead to delays in servicing the equipment and could be subject to additional charges.

Yes	No	Review the actions below and answer "Yes" or "No". Provide explanation for any "No" answers in box below.
○	○	**Instrument has been cleaned of hazardous substances**. Rinse tubing or piping, wipe down scanner surfaces, or otherwise make sure removal of any dangerous residue. Make sure the area around the instrument is clean. If radioactivity has been used, perform a wipe test or other suitable survey.
○	○	**Adequate space and clearance is provided to allow safe access** for instrument service, repair or installation. In some cases this may require customer to move equipment from normal operating location prior to Cytiva arrival.
○	○	**Consumables, such as columns or gels, have been removed or isolated from the instrument and from any area that may impede access to the instrument.**
○	○	**All buffer / waste vessels are labeled. Excess containers have been removed from the area to provide access.**
Provide explanation for any "No" answers here:		

Equipment type / Product No:		Serial No:	

I hereby confirm that the equipment specified above has been cleaned to remove any hazardous substances and that the area has been made safe and accessible.

Name:		Company or institution:	
Position or job title:		Date (YYYY/MM/DD):	
Signed:			

Cytiva and the Drop logo are trademarks of Global Life Sciences IP Holdco LLC or an affiliate.

© 2020 Cytiva.
All goods and services are sold subject to the terms and conditions of sale of the supplying company operating within the Cytiva business. A copy of those terms and conditions is available on request. Contact your local Cytiva representative for the most current information.

For local office contact information, visit cytiva.com/contact.
28980026 AD 04/2020

Product return or servicing

cytiva

Health & Safety Declaration Form for Product Return or Servicing

Return authorization number:		*and/or* **Service Ticket/Request:**	

To make sure the mutual protection and safety of Cytiva personnel, our customers, transportation personnel and our environment, all equipment must be clean and free of any hazardous contaminants before shipping to Cytiva. To avoid delays in the processing of your equipment, complete this checklist and include it with your return.

1. Note that items will NOT be accepted for servicing or return without this form
2. Equipment which is not sufficiently cleaned prior to return to Cytiva may lead to delays in servicing the equipment and could be subject to additional charges
3. Visible contamination will be assumed hazardous and additional cleaning and decontamination charges will be applied

Yes	No	Specify if the equipment has been in contact with any of the following:	
◯	◯	Radioactivity (specify)	
◯	◯	Infectious or hazardous biological substances (specify)	
◯	◯	Other Hazardous Chemicals (specify)	

Equipment must be decontaminated prior to service / return. Provide a telephone number where Cytiva can contact you for additional information concerning the system / equipment.

Telephone No:		
Liquid and/or gas in equipment is:	☐	**Water**
	☐	**Ethanol**
	☐	**None, empty**
	☐	**Argon, Helium, Nitrogen**
	☐	**Liquid Nitrogen**
	Other, specify	

Equipment type / Product No:		**Serial No:**	

I hereby confirm that the equipment specified above has been cleaned to remove any hazardous substances and that the area has been made safe and accessible.

Name:		**Company or institution:**	
Position or job title:		**Date (YYYY/MM/DD)**	
Signed:			

Cytiva and the Drop logo are trademarks of Global Life Sciences IP Holdco LLC or an affiliate.

© 2020 Cytiva.
All goods and services are sold subject to the terms and conditions of sale of the supplying company operating within the Cytiva business. A copy of those terms and conditions is available on request. Contact your local Cytiva representative for the most current information.

For local office contact information, visit cytiva.com/contact.
28980027 AD 04/2020

To receive a return authorization number or service number, call local technical support or customer service.

Index

T

U

V

W

cytiva

Give feedback on this document

Visit cytiva.com/techdocfeedback or scan the QR code.

cytiva.com/biacore

Cytiva and the Drop logo are trademarks of Life Sciences IP Holdings Corp. or an affiliate doing business as Cytiva.

Biacore is a trademark of Global Life Sciences Solutions USA LLC or an affiliate doing business as Cytiva.

Microsoft, SQL Server, and Windows are registered trademarks of Microsoft Corporation.

All other third-party trademarks are the property of their respective owners.

© 2020–2022 Cytiva

Any use of Biacore Insight is subject to Cytiva Standard Software End-User License Agreement for Life Sciences Software Products. A copy of this Standard Software End-User License Agreement is available on request.

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

29286967 AD V:13 08/2022