cytiva

Biacore X100

Operating Instructions

Original instructions

cytiva.com

Table of Contents

1 Introduction

About this chapter

This chapter contains important user information, descriptions of safety notices, regulatory information, intended use of the Biacore™ X100, and lists of associated documentation.

In this chapter

1.1 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.

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.

1.2 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

Biacore X100 is a system for real-time label-free analysis of molecular interactions in laboratory research. Biacore X100 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 Biacore X100 in the way it is intended:

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

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.

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

Biacore X100 system together with operation of the Control and Evaluation Software is described in full in the *Biacore X100 Handbook* .

Sensor surface preparation and general methodology for Biacore applications are described in the *Biacore Sensor Surface Handbook* and the *Biacore Assay Handbook* respectively. Methodology for concentration measurement using Biacore systems is described in the *Biacore Concentration Analysis Handbook* .

Data files, application notes and user documentation on the web

To order or download data files, application notes or user documentation, see the instruction below.

Step	Action
1	Go to cytiva.com/biacore.
2	Click ***Biacore X100*** .
3	Click ***RELATED DOCUMENTS***.
4	Select to download the chosen literature.

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.

Important

WARNING

Before installing, operating or maintaining the product, all users must read and understand the entire contents of this chapter to become aware of the hazards involved.

In this chapter

2.1 Safety precautions

Introduction

Biacore X100 is powered by mains voltage and handles materials that can be hazardous. Before installing, operating or maintaining the system, you must be aware of the hazards described in this manual.

Follow the instructions to avoid injury to the operator or other personnel, damage to samples or other substances handled by the equipment, to the product, or to other equipment in the area.

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

- General precautions
- Flammable liquids and explosive environment
- Personal protection
- Installing and moving the product
- Operation
- Maintenance

General precautions

WARNING

Only properly trained personnel may operate and maintain the product.

WARNING

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

WARNING

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

WARNING

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

WARNING

Use only mains cables supplied or approved by Cytiva.

WARNING

Do not block the rear or side panels of the instrument. The power switch must always be easy to access. The power cord must always be easy to disconnect.

WARNING

Decontaminate the equipment before decommissioning to make sure that hazardous residues are removed.

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

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

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 capped vials in the sample rack.

WARNING

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

Personal protection

WARNING

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

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.

CAUTION

The products that are used with toxic or hazardous substances shall 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 the product

CAUTION

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

CAUTION

Heavy object. Use proper lifting equipment, or use two or more persons when moving the instrument. All lifting and moving must be performed in accordance with local regulations.

CAUTION

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

Operation

WARNING

Handle bottles carefully. Accidental breakage of buffer or water bottles may cause flooding of the bottle tray, and liquid may come into contact with electrical circuits, causing electric shock and/or fire hazards.

WARNING

A fume hood or similar ventilation system shall be installed when flammable or noxious substances are used.

CAUTION

Accidental breakage of buffer or water bottles may cause flooding of the bottle tray, and liquid may enter the instrument enclosure. If this happens, disconnect the instrument from the mains power and call your local service representative.

CAUTION

Do not touch the pumps while they are moving.

CAUTION

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

CAUTION

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

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

The injection needle is sharp. Take care when working in the sample compartment.

WARNING

If the instrument may be contaminated with biohazards, decontaminate the instrument before performing maintenance on any instrument parts. Contact your local service representative for further information about decontamination procedures.

2.2 Labels

Introduction

This section describes the system label and other safety or regulatory labels that are attached to the product.

System label

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.

Description of symbols on the system label

The following symbols may be present on the system label.

Symbol/text	Meaning
	**Warning!** Read the user documentation before using the system. Do not open any covers or replace parts unless specifically stated in the user documentation.
Code no	Instrument assembly number
Serial no	Instrument serial number
Mfg. Year	Year (YYYY) and month (MM) of manufacture
Voltage **Frequency** **Max Power**	Electrical requirements: • Mains voltage (VAC ~) • Frequency (Hz) • Maximum power (VA)

2.3 Emergency procedures

Introduction

This section describes how to shut down the Biacore X100 system in an emergency situation, and the procedure for restarting the Biacore X100 system.

The section also describes the result in the event of power failure.

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.

To stop a run under controlled conditions before it is complete, choose ***Run →Stop Run Sensorgram*** from the menu bar in Biacore X100 Control Software. This will stop both the run and the data collection at the end of the current cycle. A dialog is displayed while the current cycle is finished.

Emergency shutdown

In an emergency situation, follow the steps below to stop the run.

Step	Action
1	Press ***Ctrl-Break (Ctrl-Pause)*** on the keyboard to stop the run and the data collection immediately.
2	In the dialog box that appears, click ***Yes*** if you want to wash the system with running buffer. You should do this if possible. The wash operation takes about 3 minutes.

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 X100 instrument	• The run is interrupted immediately. • Data collected up to and including the last cycle completed before the power failure is saved in the result file.
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 result file, but there is a risk that the result file may be corrupt and cannot be read.

Restart procedure

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

Step	Action
1	Turn on mains power if it is switched off and check that the instrument starts normally.
2	If you need to clean the liquid handling system, eject the sensor chip and insert a maintenance chip. See *Section 6.3 Cleaning, on page 52* for further instructions.

3 System description

About this chapter

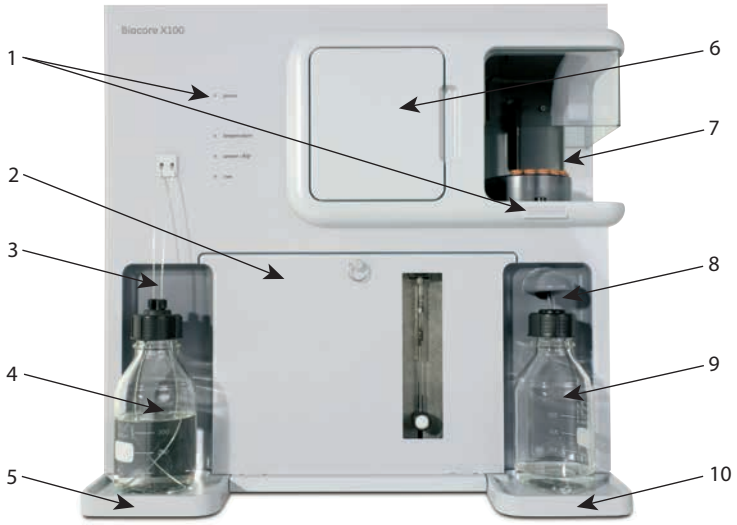
This chapter gives an overview of the Biacore X100 system, and a brief description of its function.

In this chapter

3.1 Biacore X100 instrument

Main parts of the instrument

The main parts of the instrument are identified below.



Part	Function
1	Status indicators
2	Lower front door with pump compartment and optional degasser (included in Biacore X100 Plus Package) behind
3	Buffer tubes
4	Buffer bottle
5	Buffer tray
6	Upper front door with sensor chip port behind
7	Sample compartment with sample rack
8	Waste tubing
9	Waste bottle
10	Waste tray

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

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

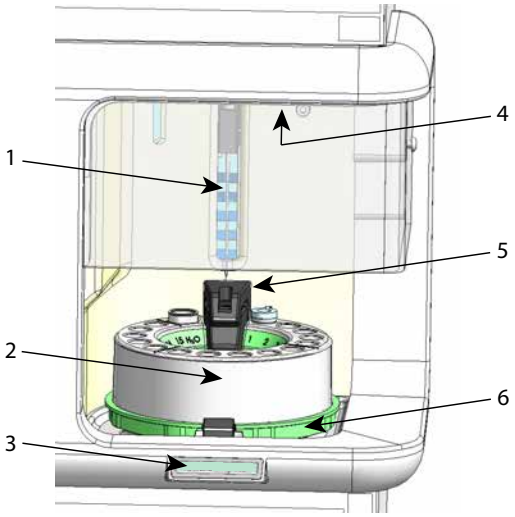
CAUTION

Accidental breakage of buffer or water bottles may cause flooding of the bottle tray, and liquid may enter the instrument enclosure. If this happens, disconnect the instrument from the mains power and call your local service representative.

CAUTION

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

Sample compartment



Part	Function
1	Injection needle (delivers samples and reagents to the chip)
2	Sample rack
3	Rack locked indicator lamp
4	Iluminating lamps in the sample compartment ceiling (turn on/off from the Control Software)
5	Needle wash station (for automatic needle wash)
6	Rack base with lock (locked/unlocked via Control Software)

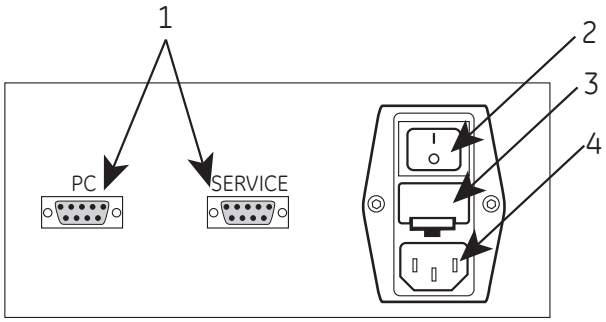
NOTICE

Do not touch the rack when the **Rack locked** indicator on the front panel is lit. The rack moves at times during the run and the needle may be destroyed if the rack is prevented from moving.

Do not attempt to rotate the rack by hand in the instrument.

Connections

Connections for mains power and computer communication as illustrated below are on the rear of the instrument at the right hand side.



Part	Function
1	Computer ports
2	Mains switch

Part	Function
3	Fuse compartment
4	Mains inlet

Note: *For warning texts, see Section 6.5 Replacing the mains fuses, on page 57.*

3.2 Indicators and switches

Status indicators

The status indicators on the front panel are described below.

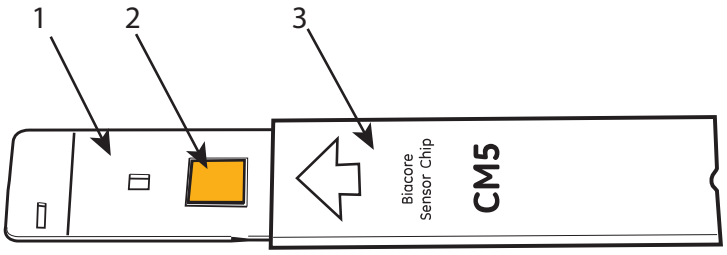
Indicator	Function
Ready (green)	Lit when power is on
Temperature (yellow)	Lit when the temperature at the flow cells is stable at the preset temperature. Flashes when the temperature is not stable.
Sensor chip (green)	Lit when a sensor chip is docked and ready. Flashing when a chip is inserted but not docked.
Run (green)	Lit when a run is in progress.

Mains power switch

The mains power connector and switch is located on the mains input panel, at the rear right of the instrument (see *Connections, on page 22*).

3.3 Sensor chip

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



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

3.4 Control system

Biacore X100 Control Software is a complete software for control and supervision of Biacore X100.

Biacore X100 Evaluation Software is a stand-alone software for evaluation of results obtained from Biacore X100. The software is normally installed on the same computer as the Biacore X100 Control Software, although connection to the instrument is not required for using Biacore X100 Evaluation Software.

All Biacore X100 Software includes an integrated support function with instructions and recommendations for using the software and also for experimental design and evaluation of results.

4 Installation

About this chapter

This chapter describes site requirements and preparations necessary to perform before installation of the Biacore X100 system.

In addition, instructions are included for moving the Biacore X100 system within the lab or to another building.

NOTICE

The product is prepared and installed by Cytiva personnel. Contact Cytiva if you require re-installation at a new site.

In this chapter

4.1 Site requirements

WARNING

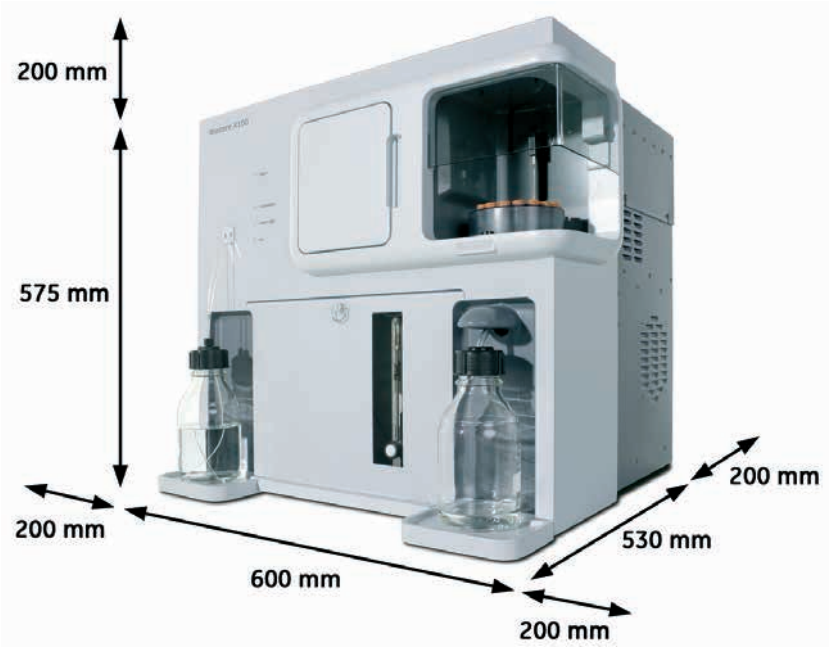
A fume hood or similar ventilation system shall be installed when flammable or noxious substances are used.

WARNING

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

Space requirements

The size of the instrument is indicated in the illustration below. At least 20 cm clearance is required on all sides of the instrument to allow adequate air circulation. Space is also required for the PC beside the instrument. The laboratory bench must be stable and able to support the weight of the instrument.



Electrical power requirements

WARNING

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

WARNING

Use only mains cables supplied or approved by Cytiva.

WARNING

Do not block the rear or side panels of the instrument. The power switch must always be easy to access. The power cord must always be easy to disconnect.

The instrument requires mains power outlets with protective earth as specified in the table below.

Parameter	Specification
Supply voltage	100 to 240 V~
Frequency	50/60 Hz
Maximum power	400 VA
Transient overvoltages	Overvoltage category II

Environmental requirements

The following general requirements must be fulfilled:

- The room must have exhaust ventilation
- The instrument should not be exposed to direct sunlight
- Dust in the atmosphere should be kept to a minimum

The installation site must comply with the following specifications:

Parameter	Specification
Allowed location	Indoor use only
Ambient temperature, operation	18°C to 33°C
Max. relative humidity, operation	80% RH, non-condensing, up to 31°C. Decreasing linearly to 50% RH at 40°C.
Ambient temperature, transportation/ storage	-25°C to 60°C
Altitude, operation	Up to 2000 m
Pollution degree of the intended environment	Pollution degree 2

Avoid placing the system adjacent to heaters or air conditioners.

Condensation may occur in the sample compartment at high ambient humidity. This is normal and does not indicate any malfunction.

4.2 Unpacking, assembly and transport

Unpacking

Biacore X100 will be unpacked by Cytiva personnel.

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

Contact Cytiva if you need to re-pack Biacore X100 for storage or transport.

Assembly

Biacore X100 requires no special assembly other than that performed by Cytiva personnel during installation.

Transport

To avoid damage, the optical unit in Biacore X100 must be secured before transport over more than limited distances within the laboratory. Contact Cytiva for assistance.

CAUTION

Heavy object. Use proper lifting equipment, or use two or more persons when moving the instrument. All lifting and moving must be performed in accordance with local regulations.

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.

4.3 Connections

NOTICE

Do not turn on the mains power switches before all connections are made.

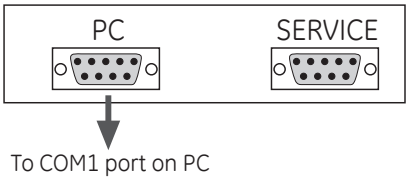
Connect the instrument to the computer

Connect a serial communication cable between the **COM1** (or **IOIOIA**) port of the PC, and the **PC** connector on the rear panel of the instrument.

The **SERVICE** connector is for service purposes only.

NOTICE

Any computer used with the equipment shall comply with IEC 60950 and be installed and used according to the manufacturer's instructions.



Connect to mains power

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

Step	Action
1	Connect the mains power cord delivered with the instrument, to the **MAINS INLET** connector on the rear panel (see *Connections, on page 22*). Connect the other end to a mains outlet with protective earth.
2	Check that any mains voltage selectors on the PC and peripheral equipment are set correctly.
3	Install the PC and peripheral equipment according to the respective instruction manuals.

WARNING

Do not block the rear or side panels of the instrument. The power switch must always be easy to access. The power cord must always be easy to disconnect.

5 Operation

About this chapter

This chapter gives instructions on how to operate the product in a safe way.

In this chapter

Safety precautions

WARNING

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

WARNING

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

WARNING

Handle bottles carefully. Accidental breakage of buffer or water bottles may cause flooding of the bottle tray, and liquid may come into contact with electrical circuits, causing electric shock and/or fire hazards.

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

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

CAUTION

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

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 shall be secured and sealed to prevent accidental spillage.

CAUTION

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

5.1 Overview

The typical workflow for performing a run in Biacore X100 is shown in the table below. Some analyses may require several runs to complete the experiment.

Stage	Description	More information
1	Create a workflow or wizard template, or use a previously saved workflow.	Biacore X100 Handbook or software support
2	Prepare buffer and samples.	*Section 5.3 Preparing, loading and changing buffers, on page 40* and *Section 5.6 Preparing and loading samples and reagents, on page 44*
3	Start the run.	*Section 5.7 Starting a run, on page 46*
4	Finish the run.	*Section 5.8 Post-run procedures, on page 47*
5	Evaluate the results.	Biacore X100 Handbook or software support

5.2 Starting the instrument

Introduction

This section describes how to start the instrument from shutdown or from standby mode.

Start the instrument from shutdown

NOTICE

If you have the Biacore X100 Plus Package, always keep the buffer tubes in liquid when the instrument is powered on to prolong the life of the degasser.

Follow the steps below to start the system from shutdown.

Step	Action
1	Switch on the printer and the PC.
2	Open the lower front door on the instrument and close the cover of the peristaltic pump. Close the door before continuing. 
3	Switch on the instrument (see *Connections, on page 22*). The status indicators on the front panel light during initiation (see *Status indicators, on page 24*). When the initiation is ready, **Power** is lit, the **Temperature** lamp is lit or flashes, **Sensor chip** is not lit or flashes and **Run** is not lit.
4	Start Biacore X100 Control Software.
5	In the login-dialog, enter your user name and password and click ***OK***. (Your user name and password are provided by your Biacore X100 administrator.)

Step	Action

If you need to select a different database connection, click ***Options>>***. The default setup is ***This machine***.

6 The software establishes connection with the instrument, which takes about 30 seconds.

7 Make sure that there is fresh buffer or water in the bottle on the left-hand tray and that both buffer tubes are inserted into the bottle.

8 Make sure that the waste bottle on the right-hand tray is empty and the waste tube is inserted in the bottle.

9 The system event log is displayed in the software and the startup procedure is recommended. Click ***Run now*** and follow the instructions on the screen. A previously used chip can be docked for the startup procedure (see *Section 5.4 Inserting a sensor chip, on page 41* for instructions on docking a sensor chip).

Once the startup procedure is finished, the instrument is automatically left in standby mode.

Start the instrument from standby

The instrument is normally left in standby mode which allows new runs to be started quickly. Follow the steps below to start from standby.

Step	Action
1	Start Biacore X100 Control Software if it is not already running.
2	In the login-dialog, enter your user name and password and click ***OK***. (Your user name and password are provided by your Biacore X100 administrator.) If you need to select a different database connection, click ***Options>>***. The default setup is ***This machine***.
3	The software establishes connection with the instrument, which takes about 30 seconds.
4	Make sure that there is fresh buffer or water in the bottle on the left-hand tray and that both buffer tubes are inserted into the bottle.
5	Make sure that the waste bottle on the right-hand tray is empty and the waste tube is inserted in the bottle.

5.3 Preparing, loading and changing buffers

NOTICE

Always use fresh water. Replace water before each run, or at least every 48 hours. Do not run the system without water.

Prepare buffer

Select buffer type depending on your specific experiments. For many protein interactions you may use HBS-EP+ buffer supplied by Cytiva.

Use degassed deionized water when preparing buffers to prevent problems with air bubbles during the run. If the instrument is equipped with the degasser provided with Biacore X100 Plus Package, you do not need to degas the water.

Always use buffer, fresh for the day and filtered through a 0.22 µm filter to remove particles. A volume of 200 mL is suitable for use during 24 hours.

Load buffer

Fill a clean buffer bottle with buffer and place it on the left-hand tray. Insert the two buffer tubes. The flow system is filled with buffer automatically when a chip is docked (see *Section 5.4 Inserting a sensor chip, on page 41*).

If the system is in standby, follow the instructions in *Start the instrument from standby, on page 38*.

Change buffer

If you need to change buffer when the instrument is in standby, select ***Tools*** →***Stop Standby*** to stop the standby and change the buffer bottle. When both buffer tubes are inserted in the new buffer, select ***Tools*** →***Prime*** to fill the system with the new buffer.

5.4 Inserting a sensor chip

Follow the steps below to insert a sensor chip into the instrument.

Step	Action
1	Open the upper front door of the instrument.
2	Click the ***Undock chip*** icon, or select ***Undock Chip*** from the ***Tools*** menu. When undocking is completed, the ***Dock Chip*** dialog is displayed and the sensor chip lamp on the front flashes. 
3	Pull out the chip slide. 
4	If required, remove the old chip. 
5	Insert the chip with the text on the upper side and the arrow pointing into the instrument. 
6	Push the chip slide all the way in.

Step	Action
	
7	Close the front door and check that the buffer tubes are placed in a bottle of buffer.
8	Complete in the information in the ***Dock Chip*** dialog and click ***Dock Chip***.

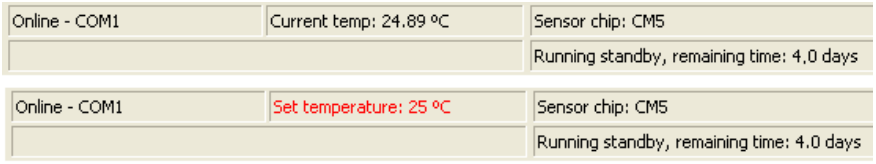
The chip is docked and the standby flow of buffer over the chip starts automatically.

5.5 Setting the analysis temperature

The SPR signal is sensitive to changes in temperature. It is important that a constant temperature is maintained at the sensor chip surface throughout the run. The detection area housing the sensor chip is maintained at a precisely controlled temperature.

The analysis temperature is fixed at 25°C in the standard instrument. With the optional Biacore X100 Plus Package, the analysis temperature can be set to 4°C to 40°C (maximum 10°C below ambient temperature).

The analysis temperature is displayed in the status bar at the bottom of the screen.



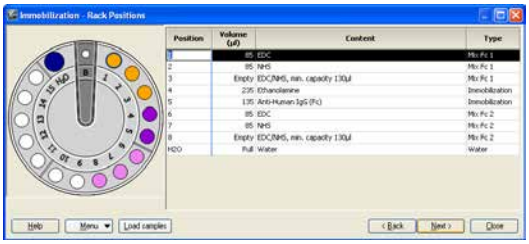
Unstable temperature is indicated by

- a flashing **Temperature** indicator on the instrument front panel,
- a flashing temperature in the Control Software status bar and
- a note in the event log in the Control Software during a run.

5.6 Preparing and loading samples and reagents

Samples and reagents

Different reagents are used depending on the type of run to be performed. The requirements for your assay are displayed in the rack position list in the Control Software when the assay is set up (see example illustration below). The list can be printed. The volumes specified in the rack position list are minimum volumes with due consideration for dead volumes. If dilution of samples is needed, dilute in degassed running buffer.



Follow the steps below to prepare samples and reagents.

Step	Action
1	Prepare the samples and reagents in 1.5 mL conical vials (available from Cytiva) according to the volumes and concentrations in the rack position list. Make sure there are no visible air bubbles in the tubes. Cap the vials to avoid evaporation during the run. Use only caps supplied for this purpose by Cytiva.
2	Fill the 4 mL vial with distilled water. Always use fresh water filtered through a 0.22 µm filter to remove particles. Do not cap the 4 mL vial! The water is used for cleaning the needle during the run and during standby.
3	Load the rack as described below.

Load the rack

Follow the steps below to load the rack in the instrument.

Step	Action
1	Click ***Load Samples*** in the ***Rack Positions*** dialog. You can also load the rack using the ***Load Samples*** icon in the toolbar if you do not have an application wizard open.
2	Wait until the **Rack locked** indicator below the rack compartment is switched off.

Step	Action
3	Lift out the rack and place the sample and reagent vials and the water vial according to the rack position list.
4	Insert the rack in the sample compartment and make sure it sits properly on the rack base.
5	Click ***OK*** in the ***Load Samples*** dialog.

5.7 Starting a run

Runs are programmed and started from a workflow, an application wizard or via a manual run. Details of how to program a run may be found in the Biacore X100 Handbook and in the integrated software support.

Before starting a run:

- Check that there is sufficient buffer in the buffer bottle, and that both buffer tubings are properly inserted in the buffer.
- Check that the waste bottle has sufficient space for the waste from the run and that the waste tubing is properly inserted in the bottle cap.
- Check that samples and reagents are in position in the sample rack, in properly capped vials.
- Check that an uncapped vial with water is in the rack position marked **H_2O**.
- Check that the rack is properly mounted and locked (the **Rack locked** indicator should be lit).

5.8 Post-run procedures

Introduction

After a run, take care of the chip (see below) and choose whether to leave the instrument in standby or perform a shutdown (see *Leave the instrument, on page 47*).

Remove the sensor chip

When...	Then...
The sensor chip will be reused in next run	Leave the chip in the instrument and make sure there is enough buffer in the buffer bottle for the standby period.
The sensor chip will be reused in a later run but not in the next run	Remove the chip and store the chip wet or dry according to recommendations in the *Biacore Sensor Surface Handbook* . Insert an old chip or the maintenance chip and start standby.
The sensor chip will not be used again	Leave the chip in the instrument or replace it with the maintenance chip and start standby.

Leave the instrument

When...	Then...
If the instrument will be used within 7 days	Prepare the system for standby.
If the instrument will not be used for more than 7 days	Perform a shutdown.

See *Section 6.7 Storage, on page 60* for details of these procedures.

6 Maintenance

About this chapter

This chapter summarizes user maintenance procedures. If more extensive service is required, please contact your Cytiva service representative. Complete the appropriate Health and Safety Declaration Form before contacting your local service representative or returning the system for maintenance or service.

Several maintenance operations are performed using software tools with on-screen instructions in English. See *Appendix A Software tool texts, on page 85* for these instructions in your local language.

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

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

CAUTION

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

In this chapter

6.1 Maintenance preparations

Important

Make sure that the BIAmaintenance Kit is available before starting maintenance procedures.

Regular maintenance of Biacore X100 is essential for reliable results. It is important to keep the instrument free from contamination such as microbial growth and adsorbed proteins in the liquid handling system.

Regular checks and maintenance should be done according to the schedules below. You will be reminded of the need for ***Desorb***, ***Desorb and Sanitize*** and ***System Check and Pump Calibration*** procedures via the scheduler displayed in the system event log. Do not ignore maintenance reminders for more than a day or so!

To display the system event log, click ***View*** →***System Event log***.

Safety precautions

WARNING

If the instrument may be contaminated with biohazards, decontaminate the instrument before performing maintenance on any instrument parts. Contact your local service representative for further information about decontamination procedures.

WARNING

Concentrated BIAdisinfectant solution is corrosive. The solution should be diluted shortly before use as described in the Instructions for Use provided with the product.

NOTICE

Some maintenance procedures will destroy the ligand on a prepared sensor chip. Always use the separate Sensor Chip Maintenance that is included in the Maintenance Kit unless otherwise stated.

NOTICE

Do not use BIAdesorb solution 1 at analysis temperatures below 20°C. BIAdesorb solution 1 precipitates at low temperatures.

6.2 Maintenance summary

Regular checks and maintenance should be done according to the schedule below.

Interval	Action	Required material
Daily/after each run	Empty the waste bottle	None
Weekly	Clean the flow system[1]: Insert a Sensor Chip Maintenance, select ***Tools*** →***More Tools*** →***Desorb*** and follow the instructions on the screen.	BIAdesorb solutions1 and 2, Sensor Chip Maintenance, deionized and filtered water
	Inspect tube fittings and pumps for possible leaks	None
Monthly	Clean and disinfect the flow system: Insert a Sensor Chip Maintenance, select ***Tools*** →***More Tools*** →***Desorb and Sanitize*** and follow the instructions on the screen.	BIAdesorb solutions 1 and 2, BIAdisinfectant solution, Sensor Chip Maintenance, deionized and filtered water
	Perform a ***System Check and Pump Calibration***: Insert a new Sensor Chip CM5, select ***Tools*** →***More Tools*** →***System Check and Pump Calibration*** and follow the instructions on screen.	BIAtest solution, HBS-EP + buffer, new Sensor Chip CM5
	Inspect the needle and needle wash station, and look for accumulations of salt or protein.	None
	Inspect the sample compartment, look for signs of flooding	None
	Clean the instrument cover	None

[1] For some applications, a coating of protein on the flow system walls helps to give reproducible results, and the first few cycles after ***Desorb*** may be unreliable. If you observe this behavior, run ***Desorb*** when you change your protein system rather than once a week.

6.3 Cleaning

Cleaning 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.

If necessary, clean the cover of the processing unit with a moist cloth. Use water or a mild detergent.

The buffer tray and the waste and water tray can be removed for cleaning.

If necessary, clean the waste bottle cap as follows:

Step	Action
1	Unscrew the cap from the waste 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.

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.

Clean the needle and wash station

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

The injection needle is sharp. Take care when working in the sample compartment.

Clean the needle and wash station if you see that salt or other deposits have accumulated. You will need deionized water, lint-free tissues, and an hex key to remove the shield (supplied with the instrument).

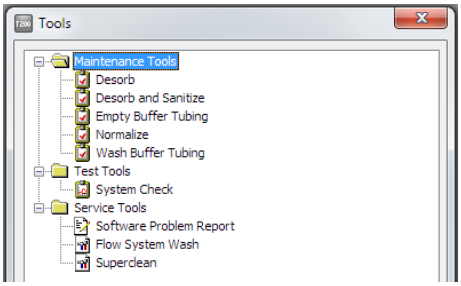
Run ***Tools*** →***More Tools*** →***Clean needle and needle wash station*** and follow the instructions on the screen.

Clean the instrument cover

If necessary, clean the cover of the instrument with a moist cloth. Use water or a mild detergent. The buffer tray and the waste tray can be removed for cleaning. If salt residues or proteins have accumulated on the buffer bottle cap, clean the cap in deionized water.

Clean and sanitize the flow system

Tools for cleaning and disinfecting the flow system are available under ***Maintenance Tools*** in the ***More Tools*** menu. For regular cleaning, use ***Desorb*** or ***Desorb and Sanitize*** from the ***Tools*** →***More Tools*** menu for cleaning and sanitizing the flow system.



The table below summarizes the tools provided.

Note: *BIAdesorb solution 1 will precipitate at low temperature and should not be used at analysis or sample compartment temperatures below 20°C. To run* ***Desorb*** *below 20°C, replace BIAdesorb solution 1 with 0.5% lithium dodecyl sulfate in water.*

Tool	Description	Required materials
Desorb	Cleans the flow system. Run at least once a week, or more often if necessary.[1]	BIAdesorb solution 1 Biadesorb solution 2
Desorb and sanitize	Cleans and disinfects the flow system. Run at least once a week, or more often if necessary.[1]	BIAdesorb solution 1 Biadesorb solution 2 BIAdisinfectant solution HBS buffer
Empty buffer tubing	Washes and empties all buffer tubing. Run whenever you intend to leave buffer tubing unused for an extended period.	70% ethanol BIAdesorb solution 2
Wash buffer tubing	Washes one or all buffer tubes. Run after using buffers containing substances that tend to adsorb to the tubing, e.g. detergent or serum albumin.	BIAdesorb solution 1 Biadesorb solution 2

[1] Use Sensor Chip Maintenance or a used chip for the procedure. The solutions used may damage the ligand on sensor chips used for assays.

Solutions for ***Desorb*** and ***Desorb and Sanitize*** are provided in the Maintenance Kit.

Use ***Superclean*** if the regular cleaning procedures are not sufficient.

The following solutions are required for the ***Superclean*** procedure:

- Deionized water (filtered 0.22 µm) at 40°C to 50°C
- 1% acetic acid
- 0.2 M sodium bicarbonate
- 6 M guanidine-HCl
- 10 mM HCl

Note: *If low molecular weight analytes have been used, use 50% DMSO and 10% DMSO instead of guanidine-HCl and HCl respectively.*

Normalizing the detector

This procedure adjusts the detector response to compensate for slight differences in individual sensor chips. For best performance, run this procedure once for each new chip. The procedure can either be run before immobilization or before the first run using the immobilized chip. Normalization injects BIAnormalizing solution (70% glycerol in water) over the chip surface.

Required solutions: BIAnormalizing solution

At the start of a run

Check the ***Normalize detector*** option in the ***System Preparations*** workspace, which appears before the start of each run.

At any other time

Run the maintenance tool ***Normalize*** to normalize the detector response for all flow cells.

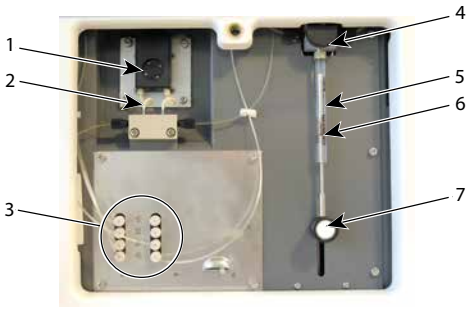
NOTICE

Run ***Normalize*** with the sensor chip that will be used for the run. Do not use Sensor Chip Maintenance for this purpose.

6.4 Component maintenance

Check for leaks

The pump compartment is placed behind the lower front door. Once a week, check that there are no liquid or salt deposits at the positions shown in the illustration below.



Part	Function
1	Peristaltic pump
2	Peristaltic pump tube fittings
3	Degasser tube fittings (only included with Biacore X100 Plus Package)
4	Syringe pump tube fittings
5	Syringe pump
6	Syringe pump barrel (below the plunger)
7	Syringe pump plunger fitting

Check system performance

Run ***System check and pump calibration*** from the ***Tools*** →***More Tools*** menu to check the peristaltic pump calibration, detector response, sample injection performance and signal noise. This tool saves the results of the test as a data item and provides a detailed report that can be priunted. If any test parameters in the report fall outside acceptance limits, contact your Cytiva representative.

6.5 Replacing the mains fuses

WARNING

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

WARNING

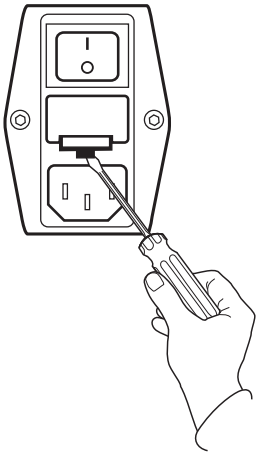
For continued protection from fire hazard, replace only with same type and rating of fuse.

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 steps below to replace the mains fuses.

Step	Action
1	Turn off the power to the Biacore X100 instrument.
2	Disconnect the mains cord from the mains power inlet.
3	Insert a small screwdriver under the tab on the fuse drawer cover.



4	Prise open the fuse drawer cover.

Step	Action
5	Replace both fuses. See the instrument product label for fuse ratings.
6	Close the fuse drawer cover and reconnect the mains supply.

6.6 Calibration

The peristaltic pump is calibrated with the ***System check and pump calibration*** tool from the ***Tools*** →***More Tools*** menu.

Needle positioning is calbrated with the ***Replace needle*** tool from the ***Tools*** →***More Tools*** menu.

All other calibration of Biacore X100 is performed by Cytiva.

6.7 Storage

Standby

Leave the system in standby mode if it is to be used within the next 7 days.

Biacore X100 is automatically placed in standby mode after the end of each run. In standby mode the instrument maintains a continuous low flow of buffer or water from the left hand bottle through the flow system to prevent accumulation of buffer residues and to preserve the ligand on the chip. Standby can run uninterrupted for up to 7 days.

If you intend to leave the instrument for up to 7 days, check that you have:

- a chip docked in the instrument
- at least 120 mL buffer or water in the buffer bottle with buffer tubes inserted
- a full water vial in the rack (the water is used for regular washes of the needle to minimize salt deposits)
- an empty waste bottle

You may restart the standby again after 7 days, after checking the list above.

Note: *We recommend that you use distilled and filtered water instead of buffer to minimize salt deposits. However, if an immobilized sensor chip is docked and will be used later, buffer may be necessary to preserve the sensor surface during standby.*

Note: *During the standby period you can leave the same buffer in the instrument for up to 7 days. However, if you start a new run, change to a buffer fresh for the day.*

Starting standby manually

To start standby manually, select ***Tools*** →***Standby*** in the Control Software. If you want to close the software but leave the instrument in standby, select ***File*** →***Exit***, choose ***Standby*** in the dialog that is displayed, and click ***Next***.

Shutdown

If the instrument is to be left unused for more than 7 days or if the instrument will be moved, perform a shutdown.

It is recommended to run ***Desorb and sanitize*** and also ***Clean needle and needle wash station*** before starting the shutdown procedure.

The shutdown procedure flushes the flow system first with distilled water, then with 70% ethanol and finally with air to dry the system.

Required materials

- Deionized water (filtered 0.22 µm)
- 70% ethanol

Shutting down the instrument

Follow the steps below to shut down the instrument.

Step	Action
1	Prepare 2 bottles: one with distilled and filtered water and the other one with 70% ethanol.
2	Choose ***File*** →***Exit*** and then select ***Shutdown*** or choose ***Tools*** →***Shutdown***. Follow the instructions on the screen. The procedure flushes the flow system and then empties the flow system of liquid. The total run time is about 10 minutes. When instructed, open the lower front door and open the cover of the peristaltic pump to release the clamping of the pump tube. 
3	Exit from Biacore X100 Control Software if it is still running.
4	Remove the bottles, and the buffer bottle cap assembly. Clean the bottle trays if required. Insert the buffer tubes in an empty bottle. The chip is undocked during the ***Shutdown*** procedure. An undocked chip is indicated with a flashing **Sensor chip** status indicator. You may remove the chip if desired: pull out the chip slide behind the upper front door and lift out the chip.

Storage conditions

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.

After storage, start up the system as described in *Start the instrument from shutdown, on page 37* and run ***System check and pump calibration*** from the ***Tools*** →***More Tools*** menu before performing any experiments.

7 Troubleshooting

About this chapter

This chapter gives a brief guide to troubleshooting procedures for problems with Biacore X100.

To avoid problems, follow the instructions and recommendations given in these Operating Instructions, and clean and maintain the instrument regularly as described in *Chapter 6 Maintenance, on page 48*. If you are experiencing problems that you cannot correct, contact your local service representative.

In this chapter

7.1 Instrument related problems

General considerations

Problem	Action
Proteins and other substances adsorb to the walls of the flow system, giving carry-over problems between assays.	Clean the flow system with ***Desorb*** more often than once a week.
Carry-over problems persist after ***Desorb and Sanitize***.	Run ***Tools*** →***More Tools*** →***Super-clean***.
Salt residues or other deposits have accumulated on the needle or needle wash station.	Clean the needle and wash station.
The needle is obstructed or damaged.	Replace the needle (***Tools*** →***More Tools*** →***Replace Needle***).
Sample consumption is unexpectedly low, sensorgrams are irregular.	Run ***Tools*** →***More Tools*** →***Flow system wash***.
The ***System Check and Pump Calibration*** shows incorrect volume delivery from the peristaltic pump.	Replace the peristaltic pump tube (***Tools*** →***More Tools*** →***Replace Peristaltic Pump Tube)***.
The syringe leaks or salt residues accumulate below the syringe piston.	Replace the pump syringe (***Tools*** →***More Tools*** →***Replace Syringe***).

Damaged needle

If the needle is damaged, check the following:

Possible cause	Action
Unsuitable caps have been used on the vials.	Ensure that only caps supplied by Cytiva are used to cap the 1.5 mL sample and reagent vials. Never cap the water vial. Change the needle as described below.
Unsuitable vials have been used.	Ensure that only recommended vials are used, see *Section 8.1 Specifications,* . Change the needle as described below.
Rack movement was obstructed during a run.	Change the needle as described below.

Possible cause	Action
The rack mechanism does not function correctly.	Contact your local Cytiva service representative.

Follow the steps below to change the needle.

Step	Action
1	To replace the needle, select ***Tools*** →***More Tools*** →***Replace Needle*** and follow the instructions on the screen.
2	When the needle replacement and calibration is finished, select ***Tools*** →***Standby*** to start standby.

System check and pump calibration

Before contacting your local service representative, run the ***System Check and Pump Calibration*** tool. The results of this procedure can help your service representative to identify problems. In some cases you may be able to correct the problem yourself.

Follow the steps below to perform a ***System check and pump calibration*** procedure.

Step	Action
1	Insert a new Sensor Chip CM5.
2	Choose ***Tools*** →***More Tools*** →***System Check and Pump Calibration***. Follow the instructions on the screen to prepare and start the procedure.
3	The results from the procedure are displayed automatically after the run. Test results are marked as ***PASS*** or ***FAIL***. If any test failed, perform the action(s) according to the table below and then repeat the ***System Check and Pump Calibration***. If the problem persists, contact your local Cytiva service representative.

Use the table below to evaluate the results of the ***System check and pump calibration*** procedure.

Failed test	Action
A: Peristaltic pump calibration	Check that the pump cover is properly closed. Check that the buffer tubes reach the buffer liquid and that they are not squeezed. Check that the pump tube does not leak and has not been punctured by mistake. If the test fails repeatedly, change the pump tube.

Failed test	Action
B: Response	If the Fc-values in the results are too low, check that you used a non-immobilized Sensor Chip CM5. If the Fc-values in the result are too low or too high, check that you used the correct buffer (HBS-EP+ buffer) and test solution (BIAtest solution).
C: Injections	Check that the tubes do not leak. Contact your local Cytiva service representative.
D: Noise	Check that you used a non-immobilized Sensor Chip CM5. Check that the temperature stability is not affected by inadequate ventilation, exposure to direct sunlight or similar.

Liquid flow problems

Problem	Possible cause	Action
Buffer is not supplied properly.	There is not enough buffer in the buffer bottle.	Ensure that there is enough buffer before starting the run.
	The cover of the peristaltic pump is not properly closed.	Close the cover.
	The flow system is leaking.	Check for leaks (*Check for leaks, on page 56*).
Air is injected during sample or reagent injections.	Insufficient volumes of sample and/or reagents.	Ensure that you use the volumes specified in the software for the run. Larger volumes may be needed if the problem persists. Ensure that you use the recommended caps for sample and reagent vials. Evaporation from uncovered vials will both affect the concentration and reduce the volume. Perform a ***System Check and Pump Calibration*** to calibrate the peristaltic pump.
Samples become cross-contaminated.	Not enough water to clean the injection needle.	Always fill the water vial in the rack before starting the run.

Temperature problems

If the analysis temperature is unstable (the **Temperature** indicator flashes) for more than one hour after the temperature has been set, check that:

- there is at least 20 cm clearance around the instrument to allow adequate circulation.
- the instrument is not placed adjacent to heaters, cooling ducts, or in direct sunlight.

Other instrument-related problems

Unexpected detection results may appear if there are dust or other particles on the sensor chip surface. Never remove the sensor chip from its protective cassette.

7.2 Other problems

Software problems

In the case of software malfunction or other software problem, run ***Tools*** →***More Tools*** →***Software Problem Report***. Complete the problem report in as much detail as you can, save the report and submit it to your local service representative. Attach any other information you think may be relevant such as screendumps or exported database items. Details of your computer, operating system and installed software are automatically included in the report.

Assay-related problems

The ***Support Navigator*** in the software provides help on assay related problems. If you cannot solve your problems with the information provided, contact your local application support specialist.

8 Reference information

About this chapter

This chapter lists the technical specifications of Biacore X100. The chapter also includes a chemical resistance guide and Health and Safety Declaration forms for service.

In this chapter

8.1 Specifications

General

Parameter	Value
Automation	Maximum 15 samples, 24 h unattended operation
Molecular weight detection	Down to 100 Da in various sample environments
Required sample volume	Injection volume + 20 to 30 µL (application dependent)
Sample/reagent capacity	15 sample/reagent vials, volume 1.5 mL 1 water vial, volume 4 mL
Analysis time per sample	Typically 5 to 15 min
Detection limit	Typically 0.1 nM for >10 000 Da analytes. Typically 1 nM for <10 000 Da analytes.
Typical range for kinetics: Association rate constant (k_a): Dissociation rate constant (k_d):	 10^3 to 10^7 $M^{-1}s^{-1}$ (for protein-protein interactions) 10^{-5} to 0.1 s^{-1}
Number of flow cells	2
Flow cell height	Approximately 0.05 mm
Flow cell volume	Approximately 0.06 µL

Instrument

Parameter	Value
Dimensions w × d × h (see also *Space requirements, on page 28*)	600 × 530 × 575 mm
Net weight	47 kg
Supply voltage	Autorange 100 to 240 V~, protective earthing
Maximum voltage fluctuation	± 10% from the nominal voltage
Frequency	50/60 Hz
Fuses	2 × T4.0AH 250 V

Parameter	Value
Maximum power consumption	400 VA
Altitiude	Up to 2000 m
Overvoltage category	II
Ambient temperature range	18°C to 33°C
Ambient humidity	≤ 80% RH
Analysis temperature	Without Biacore X100 Plus Package: 25°C. With Biacore X100 Plus Package: 4°C to 40°C, max. 10°C below ambient temperature

System controller and software

Parameter	Value
PC operating system	Microsoft Windows 7 or 10 Professional (64-bit)
Database (included)	Oracle® Database 11g Express Edition For compatibility with other Oracle database installations, contact Cytiva.
Power requirements and consumption	See manufacturer's instructions.

Sample rack

Parameter	Value
Capacity	15 sample vials + 1 water vial
Sample/reagent vials[1]	1.5 mL, conical bottom, with cap
Water vial[1]	4 mL, flat bottom, no cap

[1] Use only vials and caps from Cytiva.

Liquid containers

Parameter	Value
Running buffer	500 mL, screw cap
Waste	50 mL, screw cap

8.2 Chemical resistance

This section gives some general guidelines concerning chemical resistance for Biacore X100 components. Regarding exposure to solutions not covered by these guidelines, contact your Cytiva representative for recommendations.

The flow system and sensor chip are the only parts of Biacore X100 that come into contact with solutions. The guidelines in this section relate to tubing and connectors, selector valves, connector block, IFC and sensor chip. In most analysis situations, the ligand attached to the sensor surface limits the chemical resistance of the system as a whole.

In general, the flow system components withstand long-term exposure to common aqueous buffer solutions used in biochemical laboratories. The table below lists compatibility with other common substances.

Concentrated organic solvents as well as long-term exposure to extremes of pH (<3 and >11) should be avoided. For solutions with short-term compatibility, do not use as running buffer or for injections longer than 10 minutes. Solutions classed as long-term compatible may be used as running buffer.

Solution	Concentration	Compatibility
Acetonitrile	50%	Short term
Dimethyl formamide (DMF)	50%	Short term
Dimethyl sulfoxide (DMSO)	50% 10%	Short term Long term
Ethanol	70% 10%	Short term Long term
Ethylene glycol	100%	Short term
Formic acid	70%	Short term
Formamide	40%	Long term

8.3 Recycling information

Introduction

This section contains information about the decontamination and decommissioning of Biacore X100.

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.

Biacore X100 contains a lithium backup battery, which must not be disposed of in fire.

Disposal of batteries

Waste batteries and accumulators must not be disposed as unsorted municipal waste and must be collected separately. Follow applicable local for recycling of batteries and accumulators. Biacore X100 contains a lithium backup battery, which must not be disposed of in fire.

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 regulations and standards that apply to the product.

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.

8.4.3 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 3, premises I, office 57 Russian Federation Telephone: +7 499 609 15 50 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, город Москва вн.тер.г. муниципальный округ Таганский улица Станиславского, дом 21, строение 3, помещение I, комната 57 Российская Федерация Телефон: +7 499 609 15 50 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

8.4.4 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.

8.4.5 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.

주의사항

A급 기기 (업무용 방송통신 기자재)

이 기기는 업무용환경에서 사용할 목적으로 적합성평가를 받은 기기

로서 가정용 환경에서 사용하는 경우 전파간섭의 우려가 있습니다.

8.4.6 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)
14110073	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.

8.4.7 Other regulations and standards

Introduction

This section describes the standards that apply to the product.

Regulatory compliance of connected equipment

Any equipment connected to Biacore X100 should meet the safety requirements of IEC/EN/UL/CSA 61010-1, IEC/EN/UL/CSA 60950-1, or other relevant national safety regulations and standards. The equipment should be installed and used according to the manufacturer's instructions. Within EU, connected equipment must be CE marked.

8.5 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:			

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:			

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

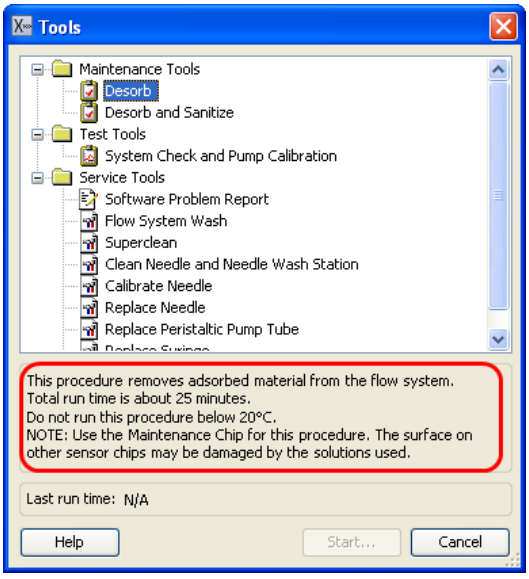
To receive a return authorization number or service number, call local technical support or customer service.

Appendix A
Software tool texts

The on-screen instructions in the maintenance, test and service software tools are given in English. Translations to other languages are provided in the local language versions of these Operating Instructions.

About this chapter

This Appendix documents the on-screen instructions in the maintenance, test and service software tools, accessed through ***Tools*** →***More Tools*** in the Biacore X100 Control Software.



In this chapter

A.1 Maintenance tools

Desorb

English text	Translation
This procedure removes adsorbed material from the flow system.	This procedure removes adsorbed material from the flow system.
Total run time is about 25 minutes.	Total run time is about 25 minutes.
Do not run this procedure below 20°C.	Do not run this procedure below 20°C.
NOTE: Use the Maintenance Chip for this procedure. The surface on other sensor chips may be damaged by the solutions used.	NOTE: Use the Maintenance Chip for this procedure. The surface on other sensor chips may be damaged by the solutions used.
Use deionized water as running buffer.	Use deionized water as running buffer.
Required solutions (from Maintenance Kit): BIAdesorb solution 1 BIAdesorb solution 2	Required solutions (from Maintenance Kit): BIAdesorb solution 1 BIAdesorb solution 2
Running Desorb procedure, please wait.	Running ***Desorb*** procedure, please wait.
The Desorb procedure is completed.	The ***Desorb*** procedure is completed.

Desorb and Sanitize

English text	Translation
This procedure removes adsorbed material and disinfects the flow system.	This procedure removes adsorbed material and disinfects the flow system.
Do not run this procedure below 20°C.	Do not run this procedure below 20°C.
NOTE: Use the Maintenance Chip for this procedure. The surface on other sensor chips may be damaged by the solutions used.	NOTE: Use the Maintenance Chip for this procedure. The surface on other sensor chips may be damaged by the solutions used.
This procedure includes 4 steps. You will need to change solutions between steps.	This procedure includes 4 steps. You will need to change solutions between steps.

English text	Translation
The total run time is about one hour followed by a recommended standby time of 3-4 hours.	The total run time is about one hour followed by a recommended standby time of 3 to 4 hours.
Do not abort this procedure after it is started.	Do not abort this procedure after it is started.
Required solutions (from Maintenance Kit): BIAdesorb solution 1, about 10 mL BIAdesorb solution 2, about 10 mL BIAdisinfectant solution, about 15 mL	Required solutions (from Maintenance Kit): BIAdesorb solution 1, about 10 mL BIAdesorb solution 2, about 10 mL BIAdisinfectant solution, about 15 mL
Place 10 mL BIAdesorb Solution 1 on the left hand tray and insert the pump inlet tubes.	Place 10 mL BIAdesorb solution 1 on the left hand tray and insert the pump inlet tubes.
Running Desorb and Sanitize procedure step 1, please wait.	Running ***Desorb and Sanitize*** procedure step 1, please wait.
Wipe the pump inlet tubes with a moist tissue.	Wipe the pump inlet tubes with a moist tissue.
Place 10 mL BIAdesorb Solution 2 on the left hand tray and insert the pump inlet tubes.	Place 10 mL BIAdesorb solution 2 on the left hand tray and insert the pump inlet tubes.
Running Desorb and Sanitize procedure step 2, please wait.	Running ***Desorb and Sanitize*** procedure step 2, please wait.
Wipe the pump inlet tubes with a moist tissue.	Wipe the pump inlet tubes with a moist tissue.
Place 15 mL diluted BIAdisinfectant Solution on the left hand tray and insert the inlet tubes.	Place 15 mL diluted BIAdisinfectant solution on the left hand tray and insert the pump inlet tubes.
Running Desorb and Sanitize procedure step 3, please wait.	Running ***Desorb and Sanitize*** procedure step 3, please wait.
Wipe the pump inlet tubes with a moist tissue.	Wipe the pump inlet tubes with a moist tissue.
Place water on the left hand tray and insert the pump inlet tubes.	Place water on the left hand tray and insert the pump inlet tubes.
Place water on the right hand tray and insert the water inlet tube.	Place water on the right hand tray and insert the water inlet tube.

English text	Translation
Running Desorb and Sanitize procedure step 4, please wait.	Running ***Desorb and Sanitize*** procedure step 4, please wait.
The Desorb and Sanitize procedure is completed.	The ***Desorb and Sanitize*** procedure is completed.

A.2 Test tools

System Check and Pump Calibration

English text	Translation
This procedure checks for leakage and tests pumps, injections and noise. The peristaltic pump is calibrated.	This procedure checks for leakage and tests pumps, injections and noise. The peristaltic pump is calibrated.
Total run time is about 35 minutes.	Total run time is about 35 minutes.
This procedure should be run at 25°C with a new Sensor Chip CM5. Running buffer should be HBS-EP+.	This procedure should be run at 25°C with a new Sensor Chip CM5. Running buffer should be HBS-EP+.
Ensure that you have HBS-EP+ as running buffer, the analysis temperature is 25°C and a new Sensor Chip CM5 is docked.	Ensure that you have HBS-EP+ as running buffer, the analysis temperature is 25°C and a new Sensor Chip CM5 is docked.
System check, please wait.	System check, please wait.

A.3 Service tools

Software Problem Report

This tool does not involve any instrument operation.

Flow System Wash

English text	Translation
This procedure washes the flow system with buffer at a high flow rate to clear any obstructions.	This procedure washes the flow system with buffer at a high flow rate to clear any obstructions.
Total run time is about 3 minutes.	Total run time is about 3 minutes.
Running Flow System Wash, please wait.	Running ***Flow System Wash***, please wait.
The Flow System Wash procedure is completed.	The ***Flow System Wash*** procedure is completed.

Superclean

English text	Translation
This procedure is for extensive cleaning of the liquid handling system. For best result run Desorb prior to Superclean.	This procedure is for extensive cleaning of the liquid handling system. For best result run ***Desorb*** prior to ***Superclean***.
Total run time is about 100 minutes.	Total run time is about 100 minutes.
NOTE: Use the Maintenance Chip for this procedure. The surface on other sensor chips may be damaged by the solutions used.	NOTE: Use the Maintenance Chip for this procedure. The surface on other sensor chips may be damaged by the solutions used.
This procedure cleans the flow system. Total run time is about 100 minutes.	This procedure cleans the flow system. Total run time is about 100 minutes.
Put the pump inlet tubes in filtered deionized warm water (40-50°C).	Put the pump inlet tubes in filtered deionized warm water (40°C to 50°C).

English text	Translation
Required solutions: 1% acetic acid 0.2 M sodium bicarbonate 6 M guanidine-HCl (or 50% DMSO) 10 mM HCl (or 10% DMSO) If small molecule assays are run, exchange the last two wash solutions for DMSO solutions.	Required solutions: 1% acetic acid 0.2 M sodium bicarbonate 6 M guanidine-HCl (or 50% DMSO) 10 mM HCl (or 10% DMSO) If small molecule assays are run, exchange the last two wash solutions for DMSO solutions.
Running Superclean procedure, please wait.	Running ***Superclean*** procedure, please wait.
The Superclean procedure is completed.	The ***Superclean*** procedure is completed.

Clean Needle and Needle Wash Station

WARNING

The injection needle is sharp. Take care when working in the sample compartment.

English text	Translation
This procedure guides the cleaning of the needle and/or the needle wash station.	This procedure guides the cleaning of the needle and/or the needle wash station.
For easier access, the transparent shield can be removed.	For easier access, the transparent shield can be removed.
During this procedure the needle will move to places not possible during normal use. Users must be extra careful. The needle is sharp and may penetrate protective latex gloves. Take particular care if infectious or toxic agents have been used.	During this procedure the needle will move to places not possible during normal use. Users must be extra careful. The needle is sharp and may penetrate protective latex gloves. Take particular care if infectious or toxic agents have been used.
Emptying needle, please wait.	Emptying needle, please wait.

English text	Translation
Carefully clean the needle and/or the needle wash station. Use a moist, lint-free cloth.	Carefully clean the needle and/or the needle wash station. Use a moist, lint-free cloth.
Select Start when cleaning is ready.	Select ***Start*** when cleaning is ready.
Starting standby, please wait.	Starting standby, please wait.
The cleaning procedure is completed. Remember to put the shield back if it was removed.	The cleaning procedure is completed. Remember to put the shield back if it was removed.

Calibrate needle

This tool does not use translatable on-screen instructions.

Replace Needle

WARNING

The injection needle is sharp. Take care when working in the sample compartment.

English text	Translation
This procedure guides the replacement of the needle.	This procedure guides the replacement of the needle.
Warning The needle is sharp and may penetrate protective latex gloves. Take particular care if infectious or toxic agents have been used.	Warning The needle is sharp and may penetrate protective latex gloves. Take particular care if infectious or toxic agents have been used.
Unscrew the shield screw, using an Allen key, and remove the transparent shield.	Unscrew the shield screw, using an Allen key, and remove the transparent shield.
Unscrew the black nut.	Unscrew the black nut.
Lift the tubing carefully away from the needle.	Lift the tubing carefully away from the needle.
If the needle is curved, straighten it out.	If the needle is curved, straighten it out.

English text	Translation
Remove the needle by pushing it up through the needle holder.	Remove the needle by pushing it up through the needle holder.
Carefully insert the new needle. Use the slit in the ceiling if required.	Carefully insert the new needle. Use the slit in the ceiling if required.
While holding the tube, replace the ferrule and the metal ring at the end of the tube with new ones.	While holding the tube, replace the ferrule and the metal ring at the end of the tube with new ones.
Take care to fit the parts in the correct order and orientation as shown.	Take care to fit the parts in the correct order and orientation as shown.
Push down the tube in the needle holder and tighten the black nut.	Push down the tube in the needle holder and tighten the black nut.
Remount the shield and tighten the shield screw.	Remount the shield and tighten the shield screw.
Press Finish to start calibration procedure.	Press ***Finish*** to start calibration procedure.

Replace Peristaltic Pump Tube

English text	Translation
This procedure guides the replacement of the peristaltic pump tube.	This procedure guides the replacement of the peristaltic pump tube.
Remove the pump inlet tubes from the buffer bottle and allow them to hang in the air.	Remove the pump inlet tubes from the buffer bottle and allow them to hang in the air.
Select Start to empty the pump tube.	Select ***Start*** to empty the pump tube.
Emptying pump tube, please wait.	Emptying pump tube, please wait.
pen the pump compartment door and open the pump cover to release the clamping of the peristaltic pump tube.	pen the pump compartment door and open the pump cover to release the clamping of the peristaltic pump tube.
Release the old pump tube from its connections and remove it.	Release the old pump tube from its connections and remove it.
Connect the new pump tube to the two metallic tubing connectors.	Connect the new pump tube to the two metallic tubing connectors.

English text	Translation
CAUTION! Be careful not to puncture the tube when connecting it.	CAUTION! Be careful not to puncture the tube when connecting it.
Put the tube into its place in the pump. Check that the pump tube is not twirled.	Put the tube into its place in the pump. Check that the pump tube is not twirled.
Close the pump cover to clamp the pump tube properly.	Close the pump cover to clamp the pump tube properly.
Close the pump compartment door.	Close the pump compartment door.
Insert both pump inlet tubes into the buffer bottle.	Insert both pump inlet tubes into the buffer bottle.
Select Start to fill the tubes.	Select ***Start*** to fill the tubes.
Filling tubes, please wait.	Filling tubes, please wait.
he maintenance procedure is completed.	The maintenance procedure is completed.
IMPORTANT! Run System Check to calibrate the flow rate of the peristaltic pump and check that the tube was properly connected.	IMPORTANT! Run ***System Check*** to calibrate the flow rate of the peristaltic pump and check that the tube was properly connected.

Replace Syringe

English text	Translation
This procedure guides the replacement of the pump syringe.	This procedure guides the replacement of the pump syringe.
Remove the pump inlet tubes from the buffer bottle and allow them to hang in the air.	Remove the pump inlet tubes from the buffer bottle and allow them to hang in the air.
Select Start to empty the syringe.	Select ***Start*** to empty the syringe.
Emptying syringe, please wait.	Emptying syringe, please wait.
Open the lower front door.	Open the lower front door.
Pull out the black knob in the lower end of the plunger.	Pull out the black knob in the lower end of the plunger.

English text	Translation
Unscrew the syringe from the pump head.	Unscrew the syringe from the pump head.
Pull out the plunger from the barrel and mount the O-ring on the lower end of the plunger (compare with the old syringe).	Pull out the plunger from the barrel and mount the O-ring on the lower end of the plunger (compare with the old syringe).
Replace the black gasket inside the pump head.	Replace the black gasket inside the pump head.
Screw the new syringe into the pump head. Tighten by hand only.	Screw the new syringe into the pump head. Tighten by hand only.
Push down the lower part of the plunger into the cavity.	Push down the lower part of the plunger into the cavity.
Push back the black knob to secure the plunger.	Push back the black knob to secure the plunger.
Put the pump inlet tubes back into the buffer bottle.	Put the pump inlet tubes back into the buffer bottle.
Select Start to fill the syringe.	Select ***Start*** to fill the syringe.
Filling syringe, please wait.	Filling syringe, please wait.
The maintenance procedure is completed.	The maintenance procedure is completed.
Check that no liquid has leaked out of the syringe pump during filling.	Check that no liquid has leaked out of the syringe pump during filling.
Close the lower front door.	Close the lower front door.

Index

T

W

cytiva

cytiva.com/biacore

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

28961142 AE V:6 03/2021