

Sefia Select™ module

Operating Instructions

Original instructions

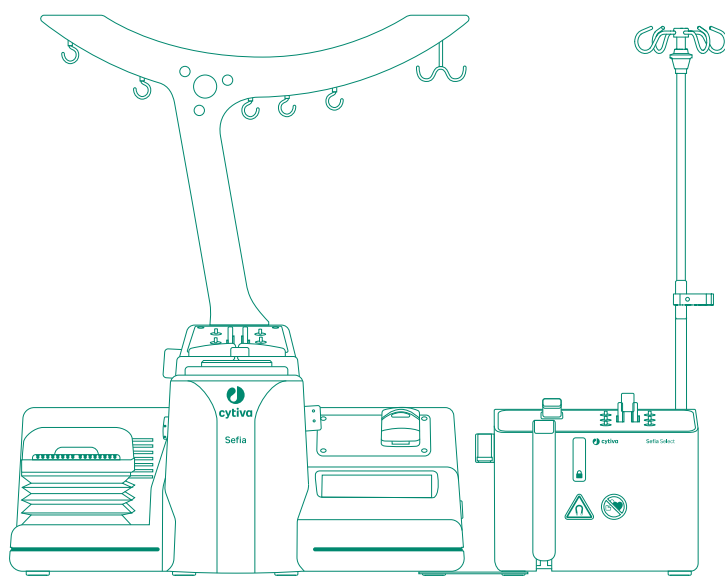


Table of Contents

1	Introduction	4
1.1	Important user information	5
1.2	About this manual	6
1.3	Associated documentation	7
2	Safety instructions	9
2.1	Safety precautions	10
2.2	Labels and symbols	13
2.3	Emergency procedures	15
3	System description	20
3.1	The Sefia Select system	21
3.2	The Sefia Select module	22
3.3	Accessories	25
3.4	Applications and kits	27
4	Installation	28
4.1	Site preparation	30
4.1.1	Space requirements	31
4.1.2	Site environment	33
4.1.3	Electrical power requirements	35
4.2	Moving the Sefia Select system	36
4.3	Electrical connections	42
5	Operation	44
5.1	Start-up and shutdown	45
5.2	Perform a run	46
6	Maintenance	47
6.1	Safety precautions	48
6.2	Cleaning and disinfection	49
6.3	Cleaning before planned service	51
6.4	Return the Sefia Select module for service	52
7	Troubleshooting	54
8	Reference information	55
8.1	System specifications	56
8.2	Recycling information	57
8.3	Regulatory information	58
8.3.1	Contact information	59
8.3.2	European Union and European Economic Area	60
8.3.3	Great Britain	61
8.3.4	Eurasian Economic Union (Евразийский экономический союз)	62
8.3.5	North America	64
8.3.6	China	65
8.3.7	South Korea	68

8.3.8	General regulatory statements	69
8.4	Health and Safety Declaration Form	70

1 Introduction

About this chapter

This chapter contains important user information that you must read before operating the Sefia Select™ module, and information about the user documentation.

In this chapter

Section		See page
1.1	Important user information	5
1.2	About this manual	6
1.3	Associated documentation	7

1.1 Important user information

Introduction

This section contains important user information about the product and this manual.

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 operate the product in any other way than described in the user documentation. If you do, you may be exposed to hazards that can lead to personal injury and you may cause damage to the cells or the cell processing equipment.

In addition, all users must read the *Sefia™ S-2000 cell processing instrument Operating Instructions (29315810)*, the *Operator Manual* for the application, and the *Instructions for Use* for the processing kit, before operating the system.

Intended use of the product

The Sefia Select module is an extension module for the Sefia S-2000 cell processing instrument.

The Sefia Select module allows for versatile combinations of multiple processing steps, including, but not limited to, magnetic isolation and formulation.

The Sefia Select module is intended for research or cellular product manufacturing use. The Sefia Select module shall not be used in clinical procedures, or for diagnostic purposes.

Prerequisites

In order to operate the Sefia Select module in the way it is intended:

- The user must have a general understanding of cell processing, and knowledge about local practices for biosafety.
- The user must read and understand the *Safety instructions* chapter in these *Operating Instructions*.
- The Sefia Select module must be installed in accordance with the site requirements and instructions in these *Operating Instructions*.

1.2 About this manual

Introduction

This section contains information about the purpose and scope of this manual, notes and tips, and typographical conventions.

Purpose of this manual

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

Scope of this manual

This manual covers the Sefia Select module, which is an extension module for the Sefia S-2000 cell processing instrument.

The Sefia S-2000 cell processing instrument is also referred to as the Sefia instrument.

The Sefia instrument, together with the Sefia Select module, is referred to as the Sefia Select system.

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.*

Typographical conventions

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

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

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`).

Tip: *The text can include clickable hyperlinks to reference information.*

1.3 Associated documentation

Introduction

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

User documentation for Sefia Select module

The user documentation is listed in the table below. English and translated versions of the *Operating Instructions* are provided on the USB flash drive located in the instrument box.

Documentation	Main contents
<i>Sefia Select module Operating Instructions (29417241)</i> (this document)	Information needed to install, operate, and maintain the Sefia Select module in a safe way. Translated versions of the original instructions are provided on the Sefia Select module User Documentation USB flash drive.
<i>Sefia S-2000 cell processing instrument Operating Instructions (29315810)</i> , delivered with the Sefia instrument	Information needed to operate and maintain Sefia instrument in a safe way. This document is referred to as <i>the Sefia instrument Operating Instructions</i> in this document
<i>Sefia Select system Site Preparation Guide (29703494)</i>	Information needed to prepare the site for installation and use of the Sefia Select system.
<i>Sefia MagnetSelect application Operator Manual (29411727)</i> , delivered with the MagnetSelect application.	Information needed to install the CT-400.1 kit on the Sefia instrument and the Sefia Select module, and run MagnetSelect on the Sefia Select system.
<i>Sefia ReadySelect application Operator Manual (29479384)</i> , delivered with the ReadySelect application.	Information needed to install the CT-350.1 kit on the Sefia instrument and the Sefia Select module, and run ReadySelect on the Sefia Select system.
<i>Instructions for Use</i> for the kit used with the application, delivered with the processing kit.	Overview of the processing kit. Information important for the safe handling, unpacking and preparation of the processing kit.

Access user documentation online

Scan the QR code or visit cytiva.com/instructions. Enter the title or the document number to access the file.



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.

In this chapter

Section	See page
2.1 Safety precautions	10
2.2 Labels and symbols	13
2.3 Emergency procedures	15

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

Follow the instructions to avoid injury to the operator, or damage to the equipment or the cell product processed by the equipment.

Before installing, operating or maintaining the system, you must be aware of the hazards described in this manual.

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

The following general precautions must be considered at all times. Precautions related to specific operations are shown in the respective chapter or section.



WARNING

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

**WARNING**

Only properly trained personnel are allowed to operate and maintain the product.

**WARNING**

Accessories. Use only accessories supplied or recommended by Cytiva.

**WARNING**

Do not use the product if it is not working properly, or if it has suffered any damage including:

- damage to the power cord or its plug,
- damage caused by dropping the product,
- damage caused by splashing liquid onto the product.

**WARNING**

Always use appropriate Personal Protective Equipment (PPE) during operation and maintenance of this product.

**CAUTION**

Keep all body parts out of the column holder slot to avoid exposure to a magnetic field stronger than the recommended levels in IEEE C95.6-2002, but below 800 mT.

**CAUTION**

Magnets produce a far-reaching, strong magnetic field. Keep the Sefia Select module at a safe distance of 10 cm or more from sharp objects that could be attracted by magnetic fields. This includes, but is not limited to: screwdrivers, scissors, keys, knives, cutters, and blades.



WARNING

Strong magnet. A permanent magnet is present in the Sefia Select module.

The magnetic field can interfere with the functioning of implanted electronic medical devices and implants containing ferromagnetic materials, such as pacemakers or implanted heart defibrillators, and can be harmful to pregnant women. It can cause **DEATH** or **SERIOUS INJURY**.

Keep a safe distance of 30 cm or more from the instrument to avoid exposure of magnetic field greater than 0.5 mT. Warn people who wear implanted electronic medical devices and implants containing ferromagnetic materials, and pregnant women, from not getting within 30 cm of the instrument.



NOTICE

Magnets produce a far-reaching, strong magnetic field. Keep the Sefia Select module at a safe distance of 10 cm or more from devices and objects that could be damaged by magnetic fields. This includes, but is not limited to: computers, computer hard drives, magnetic cards, data storage media, ISO 768 complaint mechanical watches, hearing aids, and speakers. Particularly sensitive devices and objects may require a greater safety distance and are not recommended for use in the vicinity of the Sefia Select module.

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 following symbols and text may be present on the nameplate:

Symbol / text	Description
	Product number.
	Serial number.
	Date of manufacture.
	Warning! Permanent magnet inside.
	Warning! Danger to implanted electronic medical device users (including but not limited to pacemakers or implanted heart defibrillators) and users of implants containing ferromagnetic materials, due to the permanent magnet. Implanted electronic medical device users and users of implants containing ferromagnetic materials must not get within 30 cm of the Sefia Select module.

Symbol / text	Description
	Warning! Read the user documentation before using the system. Do not open any covers or replace parts unless specifically stated in the user documentation.
Input	Electrical rating: Voltage (VAC), Frequency (Hz), Max. power (VA).
Fuse	Fuse rating: number of fuses, type T (fast), current rating (A), E (enhanced breaking capacity), voltage rating (V).
	Name and address of the manufacturer.

2.3 Emergency procedures

Introduction

This section describes how to shut down the Sefia Select system or abort an ongoing procedure in an emergency situation, and how to restart the Sefia Select system. The section also describes the result in the event of power failure.

Precautions



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.

Emergency shutdown



WARNING

In an emergency situation, follow the emergency shutdown procedure. Do not continue to use the system.

To shut down the instrument in an emergency situation, disconnect the power cords of the Sefia instrument and the Sefia Select module from the grounded wall outlets.

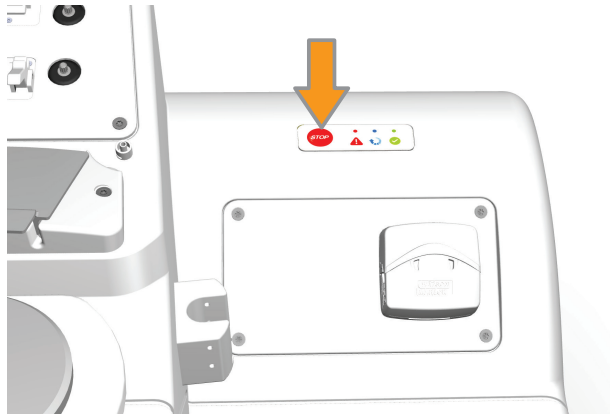
Before restarting, press the power switches on the backs of both the Sefia instrument and the Sefia Select module to the OFF position (O).

Emergency stop during a procedure

If the Sefia instrument and software is functioning, follow the steps below to abort a procedure.

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

- | | |
|---|---|
| 1 | Press the STOP button (or tap STOP on the user interface) to abort the procedure. |
|---|---|



Note:

*If you tap **STOP** on the user interface, the procedure does not stop until the on-screen pop-up is confirmed. You must confirm the interruption of the procedure by tapping **Continue**.*



Result:

The procedure stops. All stopcocks automatically move to the closed configuration.

- | | |
|---|---|
| 2 | Close all clamps on the processing kit. |
| 3 | Tap OK on the user interface. |
| 4 | If both the STOP button and STOP on the user interface are not functional, close all clamps on the processing kit and see Emergency shutdown, on page 15 to shut down the instrument. |
| 5 | Refer to the troubleshooting procedures in the application <i>Operator Manual</i> to recover the cellular product. |

Power failure

The following table describes the consequences of a power failure.

Power failure to...	Will result in...
Sefia Select module 	<ul style="list-style-type: none"> The procedure is interrupted immediately. To prevent any leakage, close all clamps on the single-use kit. The magnet remains in engaged position, and the column holder cannot be removed. The procedural data collected up to the time of the power failure is available in the logfile.
Sefia instrument 	<ul style="list-style-type: none"> The procedure is interrupted immediately. To prevent any leakage, close all clamps on the single-use kit. The procedural data collected up to the time of the power failure is available in the logfile.

Note: Connecting the Sefia Select system to an uninterruptible power supply (UPS) can help to prevent loss of data and material during a power failure.

Restart after emergency shutdown or power failure

When power is restored after a power failure or emergency shutdown, perform the actions below as required:

- Restart the Sefia Select module if necessary.
- Restart the Sefia instrument and the application software.
- Refer to the troubleshooting procedures in the application *Operator Manual* to recover the cellular product.

Disengaging the magnet



WARNING

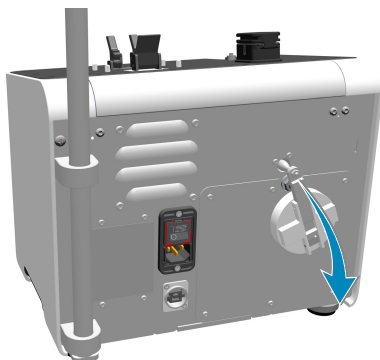
The handle of the crank must be folded in during operation and transport of the Sefia Select module.

A crank for manually disengaging the magnet is located at the back of the Sefia Select module.

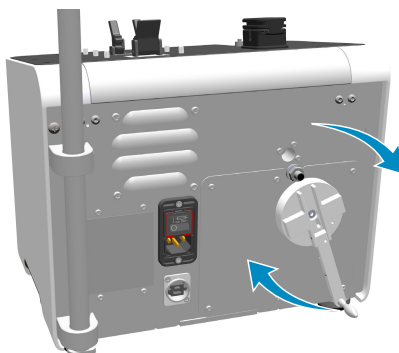
In an emergency, if the column holder must be removed, or if the Sefia Select module must be returned, disengage the magnet into a rest position following the steps below.

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

- | | |
|---|--|
| 1 | Fold out the handle of the crank on the back of the Sefia Select module. |
|---|--|



- | | |
|---|--|
| 2 | Turn the crank handle clockwise (CW) until it stops. |
|---|--|



Result:

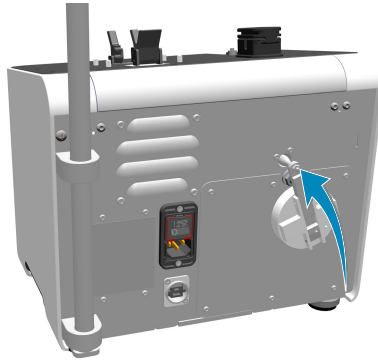
The magnet is moved away from the magnetic bead column.

Note:

The magnet can only be moved in one direction using the crank. It is not possible to activate the magnet with the crank.

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

- | | |
|---|---|
| 3 | Fold the handle of the crank back into the original position. |
|---|---|



3 System description

About this chapter

This chapter gives an overview of the Sefia Select system, comprised of the Sefia instrument and the Sefia Select module.

In this chapter

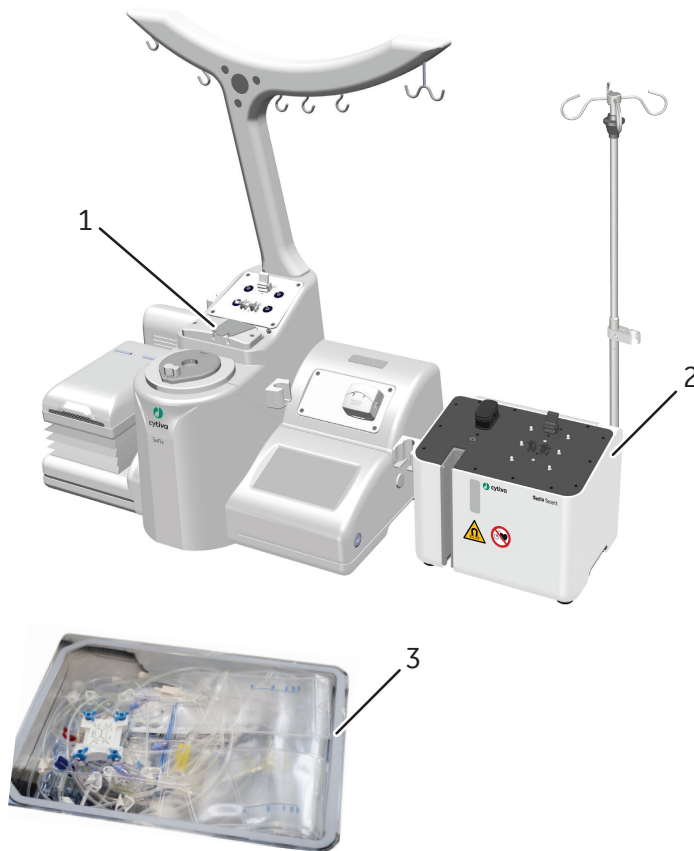
Section		See page
3.1	The Sefia Select system	21
3.2	The Sefia Select module	22
3.3	Accessories	25
3.4	Applications and kits	27

3.1 The Sefia Select system

The Sefia Select system processes cellular product and directs it into dedicated kit bags at the end of the procedure.

The illustration below shows the main parts of the Sefia Select system:

1. Sefia instrument
2. Sefia Select module
3. Single-use kit
4. Not shown: Application software



3.2 The Sefia Select module

Introduction

The Sefia Select module is an accessory that can only be used in combination with the Sefia instrument, applications, and dedicated single-use kits.

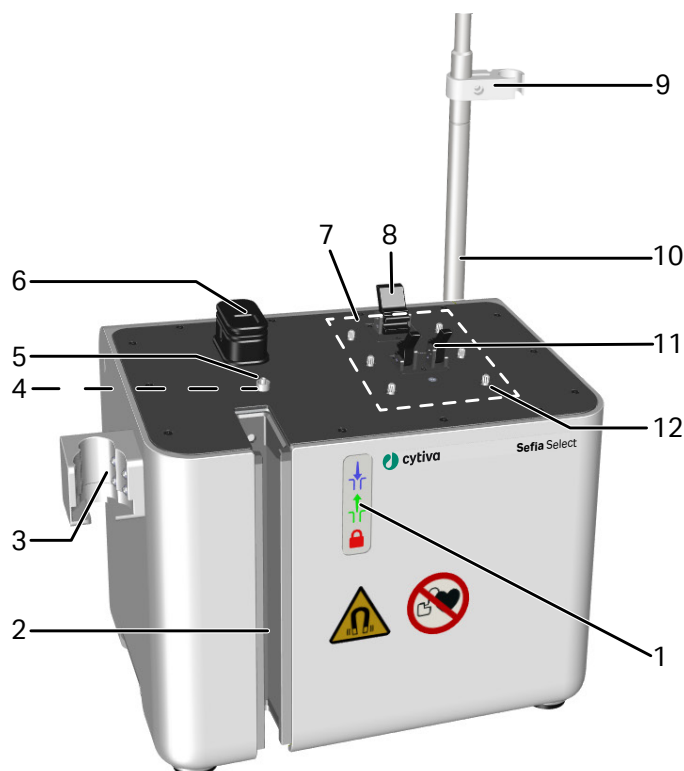
The Sefia Select module can be used for magnetic isolation of cells but also for split processing of cellular products using extra stopcocks from the module.

Main components

The Sefia Select module includes the following main components:

- Automated magnetic actuator for magnetic isolation.
- Rotary pins driven by stopcock motors, to allow automation of the liquid transfer.
- Monitoring sensors, including a pressure sensor, and an air bubble sensor.
- Dedicated electronics controlled by the Sefia instrument via USB connection.
- Power supply, independent of the Sefia instrument.

Illustration of the module, front parts



Part	Description
1	Status indicators, see description below
2	Column holder slot for a magnetic isolation column
3	Drip chamber holder
4	Line pressure sensor
5	Connector for pressure filter
6	Air bubble sensor
7	Stopcock module with six stopcock motors
8	Upper fixation lever for the stopcock cassette
9	Drip chamber holder
10	Bag pole with hooks for bags
11	Lower fixation lever for the stopcock cassette
12	Rotary pin, driven by a stopcock motor

Status indicators

The status indicators show the status of the instrument as follows:




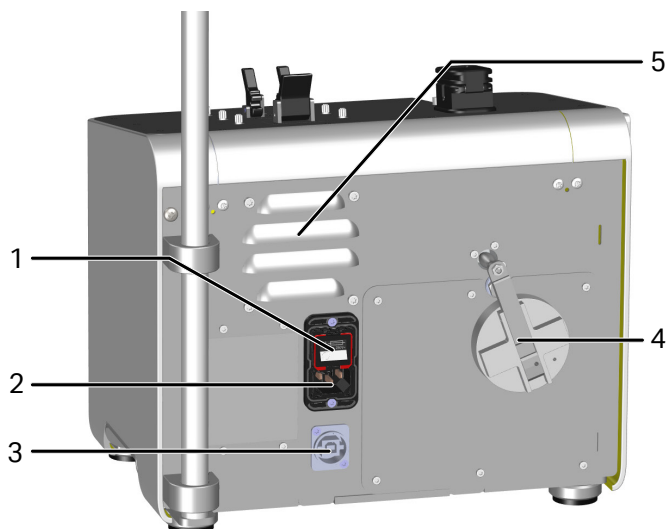

Indication	Status
	The blue pictogram is illuminated to indicate that you can insert the column holder into the slot in the Sefia Select module.
	The green pictogram is illuminated to indicate that the application has been successfully completed and the magnetic circuit is OFF. You can now remove the column holder from the Sefia Select module.
	The red pictogram is illuminated to indicate that the column holder is properly locked in place.

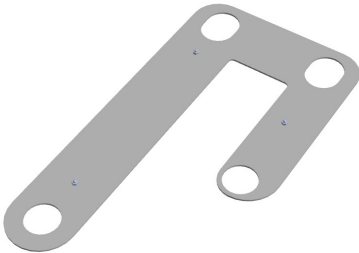
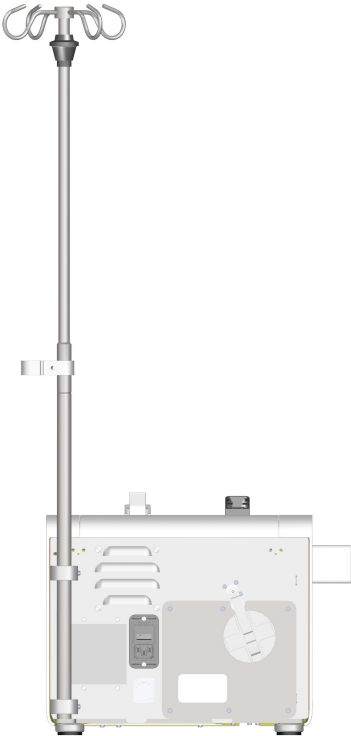
Illustration of the rear panel



Part	Description
1	<p>Power switch with two positions: ON (I) and OFF (O). The power switch is integrated with the fuse holder.</p> <div>  <p>WARNING The fuses must be replaced by authorized service personnel only.</p> </div>
2	Power input socket
3	USB port (Type B) to connect the module to the Sefia instrument
4	Crank for moving the magnet
5	Fan (air outlet). Cools the instrument. The fan is operating whenever the instrument is powered ON.

3.3 Accessories

The following accessories are included with the Sefia Select module:

Accessory	Description
<p>Connection plate</p> 	<p>Attached to the bottom of the Sefia and the Sefia Select module, to provide a fixed mechanical connection.</p>
<p>Bag pole</p> 	<p>Adjustable bag pole with four bag hooks and a drip chamber holder that attaches to the Sefia Select module.</p> <p>For height adjustment instructions, see Re-installing the Sefia Select system at a new location, on page 37.</p>



NOTICE

The bag pole holds a maximum total weight of 3 kg.

Peripherals specifications

Below is a list of all cables and other accessories.

Product number	Description	Manufacturer
6041	Power cable C13 (IEC 60320-1) Europe – 2.5 m	Schurter
6080	Power cable C13 (IEC 60320-1) North America – 3.0 m	Schurter
6081	Power cable C13 (IEC 60320-1) U.K. – 2.0 m	Schurter
6082	Power cable C13 (IEC 60320-1) China – 2.0 m	Schurter
29300935	Power cable C13 (IEC 60320-1) Japan – 2.0 m	Schurter
29689515	USB 2.0 shielded cable, AM/BM – 1.0 m	CNC Tech

3.4 Applications and kits

Applications

The Sefia instrument uses software applications that allow the instrument to perform various cell processing functions. For each application, a dedicated single-use kit is used.

Cell processing kits

All cell processing kits include one or two stopcock cassettes. Stopcock cassettes can have four or six stopcocks. The kits can also contain a separation chamber, magnetic column holder, and pre-attached bags, depending on their configuration. Each kit is supplied sterile and is for single-use only.

Each box of kits includes relevant *Instructions for Use* for that kit. Read these carefully before opening the blister pack.

Application and kit combinations



NOTICE

Only use applications and kits in the below combinations.

Note: *Cytiva is not responsible for any consequences of using any kit other than those specified in this document.*

Kit	Application
CT-350.1	ReadySelect
CT-400.1	MagnetSelect

For instructions on how to install the kit, refer to the *Operator Manual* for the application.

4 Installation

About this chapter

This chapter describes the site requirements and provides instructions for moving and re-installing the Sefia Select module, if it is moved within the laboratory or to another building.

About the installation

The initial installation will be done by Service personnel from Cytiva, or other staff who are authorized by Cytiva to install the Sefia Select module.

Note: *Save all the original packing material. If the system has to be repacked, for transportation or otherwise, it is important that the system can be safely packed using the original packing material.*

Safety precautions



WARNING

Strong magnet. A permanent magnet is present in the Sefia Select module.

The magnetic field can interfere with the functioning of implanted electronic medical devices and implants containing ferromagnetic materials, such as pacemakers or implanted heart defibrillators, and can be harmful to pregnant women. It can cause DEATH or SERIOUS INJURY.

Keep a safe distance of 30 cm or more from the instrument to avoid exposure of magnetic field greater than 0.5 mT. Warn people who wear implanted electronic medical devices and implants containing ferromagnetic materials, and pregnant women, from not getting within 30 cm of the instrument.



CAUTION

Keep all body parts out of the column holder slot to avoid exposure to a magnetic field stronger than the recommended levels in IEEE C95.6-2002, but below 800 mT.

**CAUTION**

Magnets produce a far-reaching, strong magnetic field. Keep the Sefia Select module at a safe distance of 10 cm or more from sharp objects that could be attracted by magnetic fields. This includes, but is not limited to: screwdrivers, scissors, keys, knives, cutters, and blades.

**NOTICE**

External magnetic field. Do not expose the instrument to equipment that contains magnets or generates magnetic or electromagnetic fields that can interact with the permanent magnet in the product. This includes devices such as mobile phones.

**NOTICE**

Magnets produce a far-reaching, strong magnetic field. Keep the Sefia Select module at a safe distance of 10 cm or more from devices and objects that could be damaged by magnetic fields. This includes, but is not limited to: computers, computer hard drives, magnetic cards, data storage media, ISO 768 complaint mechanical watches, hearing aids, and speakers. Particularly sensitive devices and objects may require a greater safety distance and are not recommended for use in the vicinity of the Sefia Select module.

In this chapter

Section	See page
4.1 Site preparation	30
4.2 Moving the Sefia Select system	36
4.3 Electrical connections	42

4.1 Site preparation

Introduction

This section describes the site planning and preparations necessary for the installation of the Sefia Select module. The purpose is to provide planners and technical staff with the data needed to prepare the laboratory for the installation.

The performance specifications of the system can be met only if the laboratory environment fulfills the requirements stated in this section.

See also [Section 8.1 System specifications, on page 56](#).

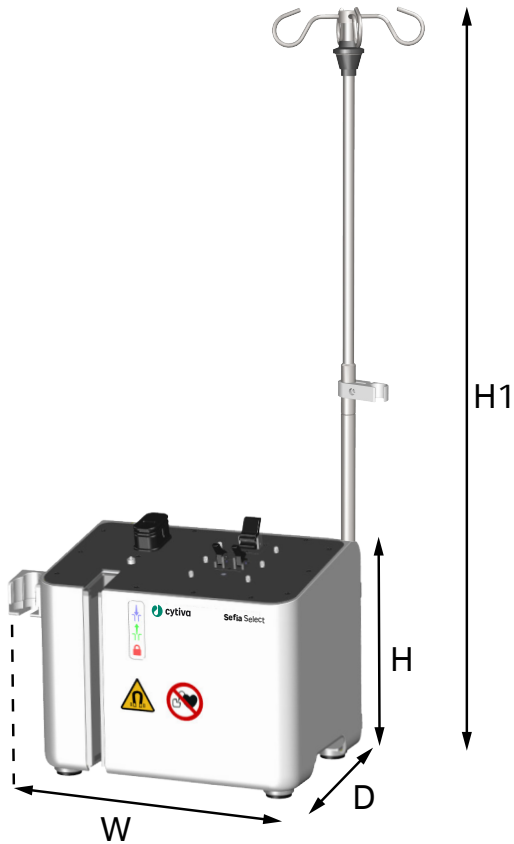
In this section

Section		See page
4.1.1	Space requirements	31
4.1.2	Site environment	33
4.1.3	Electrical power requirements	35

4.1.1 Space requirements

Dimensions and weight

The following illustration shows the dimensions of the Sefia Select module.



Parameter	Value
W	37.5 cm (14.8")
D	27 cm (10.6")
H*	30 cm (11.8")
H1	Max. 90 cm (35")
Weight	25 kg (55 lbs)

*Vertical height to the top of the fixation levers

Laboratory bench



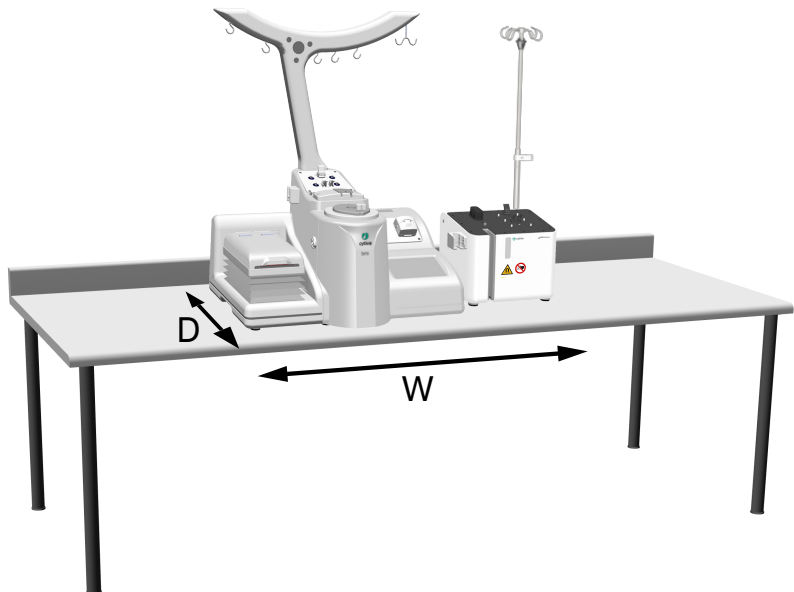
CAUTION

Make sure that the system is placed on a stable, level bench with adequate space for ventilation.

Prepare a clean working area on a stable laboratory bench with enough space for the system and accessories. The load capacity of the bench must be greater than the combined weight of all items placed on the bench. The bench must also comply with the specifications in the following table.

Parameter	Specification
Minimum bench area for operating the system (D × W)	70 × 150 cm
Free space required around the instrument	10 cm free space behind the instrument, 20 cm free space on all other sides.
Inclination of bench surface	Horizontal $\pm 2^\circ$

The following illustration shows a typical installation:



4.1.2 Site environment

Introduction

This section describes the environmental requirements for installation of the Sefia Select module.

Environmental conditions

The following general requirements must be fulfilled:

- The room must have exhaust ventilation
- The instrument should not be exposed to sources of heat, such as direct sunlight
- Dust in the atmosphere should be kept to a minimum
- The equipment must not be exposed to vibrations

Environmental requirements

Parameter	Requirement
Allowed location	Indoor use only
Ambient temperature, operation	7°C to 27°C
Ambient temperature, storage and transport	0°C to 45°C
Max. relative humidity, operation	30% to 75%, non-condensing
Relative humidity, non-operating	20% to 75%, non-condensing
Ambient atmospheric pressure, operation	840 to 1060 mbar (12 to 15 psi)
Pollution degree of the intended environment	Pollution degree 2

Instrument ventilation



NOTICE

Do not block the air vents on the rear of the instrument.

Heat output

Component	Heat output
Sefia Select module	Maximum 100 W
Sefia instrument	Maximum 1000 W

4.1.3 Electrical power requirements

Parameter	Requirement
Supply voltage	100 to 240 V~
Frequency	50/60 Hz
Transient overvoltages	Overvoltage category II
Max power consumption	100 VA

4.2 Moving the Sefia Select system

Introduction

This section gives instructions for moving the Sefia Select system within the laboratory. If you need to transport the system to another site, contact Cytiva for support.

Safety precautions



WARNING

Heavy object. Two people are needed to lift the Sefia Select module.



WARNING

Handling: When lifting and/or moving the Sefia Select module, each person lifting must position the second hand on the rounded top surface at the back of the module to stabilize the module.

Lifting the Sefia Select module

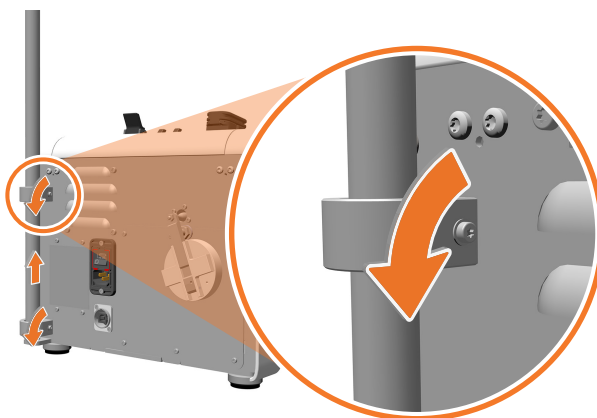
To lift the Sefia Select module, grasp the instrument at the bottom left and right sides. Place a second hand at the rounded top surface at the back of the module to stabilize (each person lifting).



For lifting the Sefia instrument, refer to the Sefia instrument *Operating Instructions*.

Moving procedure

Step	Action
1	Make sure that both the Sefia instrument and the Sefia Select module are disconnected from power.
2	Remove the USB cable between the instruments.
3	Disconnect the barcode reader and any other accessories connected to the instruments.
4	Remove the bag pole from the Sefia Select module: loosen the clamp screws and pull up the bag pole.



5	Lift the Sefia Select module and remove it from the connection plate connecting to the Sefia instrument.
6	Place the instruments on a suitable cart that can carry the weight of both instruments.
7	Move the system to a new location that fulfills the site requirements in Section 4.1 Site preparation, on page 30 .

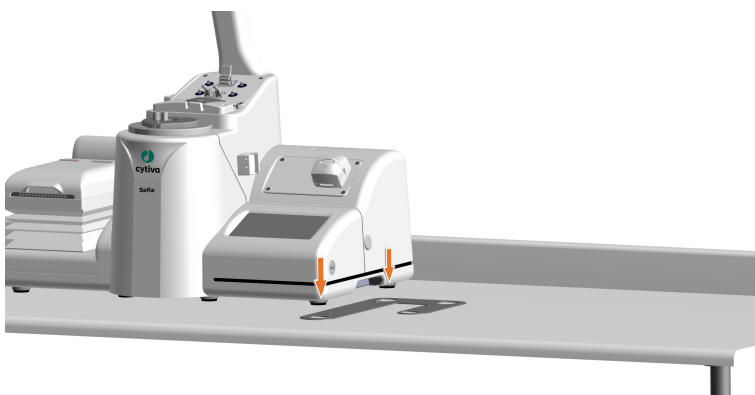
Re-installing the Sefia Select system at a new location

Follow the instructions below to re-install the Sefia Select system at the new location.

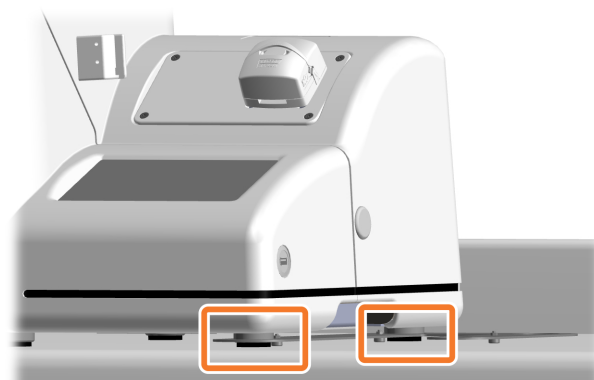
Note: *The module must always be reconnected to the same Sefia instrument.*

Step	Action
1	Place the instrument on a suitable laboratory bench in the new location.

Step	Action
2	Place the connection plate on the bench, close to the right-hand side of the Sefia instrument.
3	Lift the Sefia instrument at the right-hand side and lower it onto the connection plate.



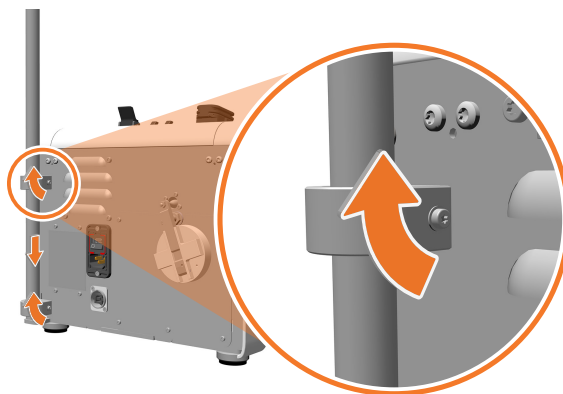
- 4 Make sure that the right feet are centered in the holes of the connection plate.



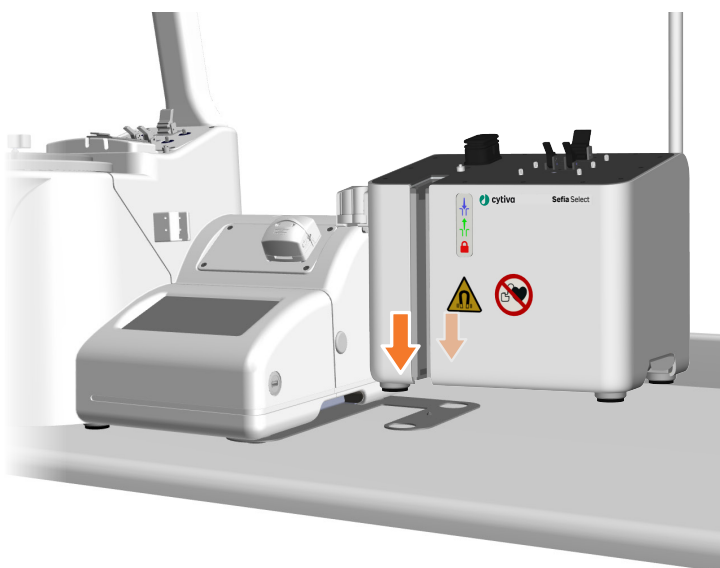
- 5 Attach the bag pole:
- Lower the bag pole through the clamp, and into the holder.

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

- | | |
|----|--|
| b. | Tighten the clamp screws with a T10 hexalobular screwdriver. |
|----|--|

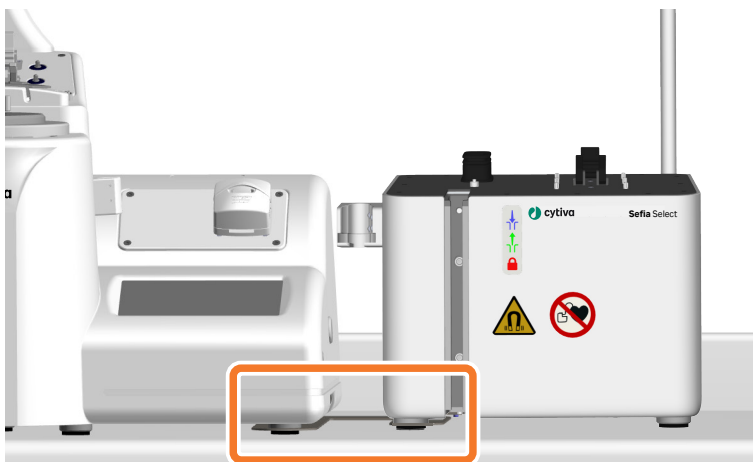


- | | |
|---|--|
| 6 | Position the Sefia Select module by inserting the feet on the left-hand side into the holes on the connection plate. |
|---|--|



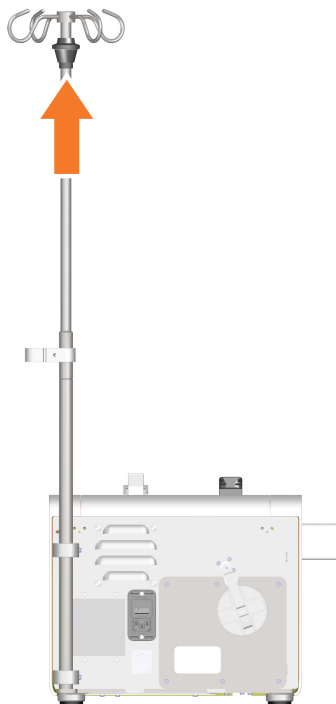
Step	Action
------	--------

- | | |
|---|--|
| 7 | Make sure that both instruments rest on the bench surface. |
|---|--|



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

- | | |
|---|---|
| 8 | Adjust the height of the bag pole by pulling upward on the black rubber part, indicated by the arrow in the illustration: |
|---|---|



- | | |
|---|--|
| 9 | Perform electrical connections, see the following section. |
|---|--|

4.3 Electrical connections

Introduction

If the Sefia Select system is moved within the lab or to another site, both instruments must be connected to electrical power and connected via the USB cable. The Sefia instrument can optionally be connected to the network. This section shows the electrical connections that must be made to the instruments.

Safety precautions



WARNING

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



WARNING

Power cord. Only use power cords with plugs delivered or approved by Cytiva.



WARNING

Supply voltage. Before connecting the power cord, make sure that the supply voltage at the wall outlet corresponds to the requirements for the instrument.

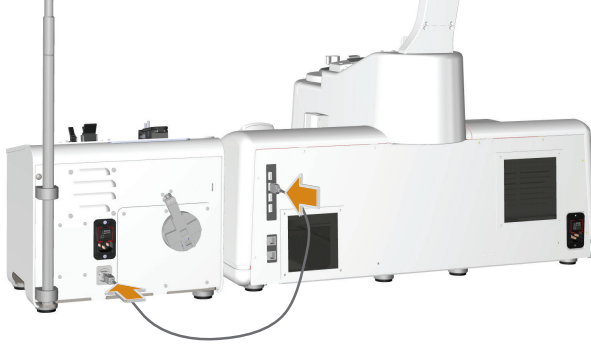


WARNING

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.

Connect the USB cable

Connect the USB cable from one of the **USB1-USB4** connectors on the rear panel of the Sefia instrument, to the USB connector on the rear panel of the Sefia Select module.



Connect power

Connect the power cables from the Sefia Select module and the Sefia instrument to separate grounded wall outlets with supply voltage corresponding to the marking on the instrument.



5 Operation

About this chapter

This chapter gives instructions on how to operate the Sefia Select module.

Detailed instructions for installing the processing kit and running the application are provided in the *Operator Manual* for the application.

Safety precautions



WARNING

Always use appropriate Personal Protective Equipment (PPE) during operation and maintenance of this product.

In this chapter

Section		See page
5.1	Start-up and shutdown	45
5.2	Perform a run	46

5.1 Start-up and shutdown

Introduction

This section gives instructions for basic operation of the Sefia Select module.

Start the Sefia Select module

Start the Sefia Select module before the Sefia instrument.
To start the Sefia Select module, switch the Power switch to the ON position (I).



Start the Sefia instrument

Follow the instructions in the Sefia instrument *Operating Instructions* to start the Sefia instrument.

Shut down the Sefia Select system

Step	Action
1	Follow the instructions in the Sefia instrument <i>Operating Instructions</i> to shut down the Sefia instrument.
2	When prompted, switch off the power switch at the back of the Sefia instrument.
3	Switch the power switch on the Sefia Select module to the OFF position (O).

5.2 Perform a run

Overview

The table below provides an overview on how to run a procedure. Refer to the *Operator Manual* of the application for more information about a specific application workflow, parameters, kit installation, and troubleshooting.

Phase	Description
1	Select the application.
2	Edit the parameter values or select a parameter group (if applicable).
3	Verify the kit and packaging, before opening the kit blister pack (e.g., integrity of the package, sterilization indicator, and expiration date).
4	Install the single-use kit components on the instrument and the module.
5	Enter the traceability values from a traceability group.
6	Verify the parameter and traceability values from the summary screen.
7	Check stopcock positions (if applicable).
8	Monitor the procedure by following the on-screen prompts.
9	Finish the procedure by following the on-screen prompts.
10	Remove the single-use kit from the instrument and the module.
11	Dispose of the single-use kit according to internally validated Standard Operating Procedures (SOP) and local regulations.

6 Maintenance

About this chapter

This chapter provides information to enable users and service personnel to clean, maintain, and store the product.

In this chapter

Section		See page
6.1	Safety precautions	48
6.2	Cleaning and disinfection	49
6.3	Cleaning before planned service	51
6.4	Return the Sefia Select module for service	52

6.1 Safety precautions



WARNING

Always use appropriate Personal Protective Equipment (PPE) during operation and maintenance of this product.



WARNING

Disconnect the product from the power supply before cleaning.



WARNING

Do not spray or pour liquids or cleaning agents directly onto the instrument.

- Spray or pour the liquid or cleaning agent onto a cloth or wipe, and then apply to the instrument.
- Do not immerse the instrument.



CAUTION

Read the instructions, guidance notes, and safety information associated with the cleaning agents and use as directed.

6.2 Cleaning and disinfection

Introduction

This section provides instructions for cleaning and disinfecting the Sefia Select module.

Clean and disinfect the Sefia Select module regularly using the procedures described in the following sections.

Recommended materials and substances

The substances listed below have been validated with all the components. Use disposable lint-free wipes for use in clean rooms.

Function	Substance
Cleaning	De-ionized or purified water
	Isopropyl alcohol (IPA) solution (up to 70% v/v)
Disinfection	Up to 6% H ₂ O ₂ (hydrogen peroxide).
	Isopropyl alcohol (IPA) solution (up to 70% v/v)

Note: Some of the substances above might alter the color or appearance of the surface finishes in the product if applied repeatedly. However, the underlying component functionality is unaffected.

Clean the instrument

Clean the Sefia Select module weekly, or after any events such as a leakage, using the following procedure.

Step	Action
1	Switch off the instrument and unplug the power cable to prevent electric shock. See Section 5.1 Start-up and shutdown, on page 45 .
2	Wipe the outside of the instrument with a damp lint-free wipe.



WARNING

Do not spray or pour liquids or cleaning agents directly onto the instrument.

- Spray or pour the liquid or cleaning agent onto a cloth or wipe, and then apply to the instrument.
- Do not immerse the instrument.

Step	Action
3	Wipe off any stains or spills using one of the recommended cleaning agents. Wipe off excess liquid.
4	Wipe the outside of the instrument with a dry, lint-free cloth.
5	Inspect to make sure that the instrument is clean. If necessary, repeat the cleaning procedure.
6	Let the cleaned surfaces dry completely before using the instrument.
7	Follow your internally validated standard operating procedure (SOP) to discard any waste.

Disinfect the instrument

Disinfect the Sefia Select module when required using the following procedure.

Step	Action
1	Follow the instructions in Clean the instrument, on page 49 to clean all accessible surfaces.
2	Wipe all accessible surfaces with a disposable lint free wipe saturated with one of the recommended disinfectants.
3	Allow the disinfectant to dry completely.
4	Wipe the disinfected surfaces with a disposable lint free wipe saturated with de-ionized or purified water, to remove any residual disinfectant.
5	Let the disinfected surfaces dry completely before using the instrument.
6	Follow your internally validated SOP to discard any waste.

6.3 Cleaning before planned service

Introduction

This section describes what to do before a planned service can be performed.

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.

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.

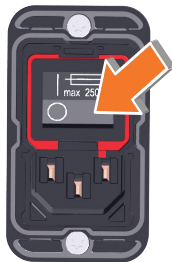
Health and safety declaration forms

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.

6.4 Return the Sefia Select module for service

If the Sefia Select module must be returned due to failure, follow the steps below to safely package the module.

Step	Action
1	Make sure that the power switch on the Sefia Select module is in the OFF position (O).



- 2 Make sure that the main power cable is disconnected.
- 3 Release the magnet by turning the crank on the back of the module clockwise until it stops. See detailed instructions in [Disengaging the magnet, on page 17](#).



WARNING
The magnet must be fully disengaged during transportation or return of the Sefia Select module. Make sure the crank on the back of the module has been rotated clockwise until it stopped and folded back.

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

- | | |
|---|---|
| 4 | Pack the Sefia Select module in the original packing material (cardboard box and form-fitting foams) in which it was delivered. |
|---|---|



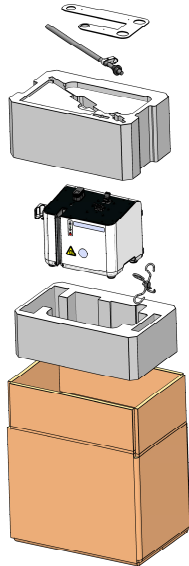
WARNING

Do not use packaging other than the original packaging provided by Cytiva, which is compliant with the air transportation requirements (IATA) for magnets.

Contact Cytiva if the original packaging is:

- damaged (including but not limited to cut, crushed, or damaged form-fitting foams),
- has been discarded, or
- has had the Cytiva label removed.

Deviation from this warning may cause harm for air transportation.



- | | |
|---|---------------------------------------|
| 5 | Contact Cytiva to arrange the return. |
|---|---------------------------------------|

7 Troubleshooting

General information

If problems occur when operating the product, warning or error messages appear on the Sefia instrument. Refer to *Troubleshooting* section of the Sefia instrument *Operating Instructions* for detailed troubleshooting procedures and information about on-screen messages.

8 Reference information

About this chapter

This chapter provides manufacturer information and lists the system specifications of the Sefia Select module. The chapter also includes recycling information and regulatory information.

In this chapter

Section		See page
8.1	System specifications	56
8.2	Recycling information	57
8.3	Regulatory information	58
8.4	Health and Safety Declaration Form	70

8.1 System specifications

Dimensions and weight

Parameter	Value
Width	37.5 cm (14.8")
Depth	27 cm (10.6")
Height, to the top of the cassette levers	30 cm (11.8")
Height, including bag pole	Max. 90 cm (35")
Weight	25 kg (55 lbs)

Power

Parameter	Value
Input voltage range	100 to 240 V~ autorange
Maximum voltage fluctuation	±10% from the nominal voltage
Frequency	50/60 Hz
Maximum power consumption	100 VA
Fuse rating	2x T3.15A E 250V

Noise level

70 dB (A) or lower.

Ingress protection

Parameter	Specification
Sefia Select module	IP21

8.2 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.

Disposal of the processing kit

After a procedure, follow your internally validated standard operating procedures to dispose of remaining parts of the processing kit.

Observe all applicable national and local environmental requirements.

Disposal of electrical components



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

8.3 Regulatory information

Introduction

This section lists the regulations and standards that apply to the product. Your system is marked or listed according to the applicable regulatory requirements for your region. Local language translations are only provided according to regulatory requirements.

In this section

Section		See page
8.3.1	Contact information	59
8.3.2	European Union and European Economic Area	60
8.3.3	Great Britain	61
8.3.4	Eurasian Economic Union (Евразийский экономический союз)	62
8.3.5	North America	64
8.3.6	China	65
8.3.7	South Korea	68
8.3.8	General regulatory statements	69

8.3.1 Contact information

Introduction

This section shows the contact information for support and manufacturing 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 the legal manufacturer	Biosafe S.A. Allée des moulins 3 1274 Grens Switzerland
Telephone number of the legal manufacturer	+41 21 560 19 00

8.3.2 European Union and European Economic Area

Introduction

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

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 product 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.

8.3.3 Great Britain

Introduction

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

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 product 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.

8.3.4 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 <i>Manufacturing information</i>
Importer and/or company for obtaining information about importer	<p>Cytiva RUS LLC</p> <p>109004, Moscow</p> <p>internal city area Tagansky municipal district</p> <p>Stanislavsky str., 21, building 5, premises I, offices 24,25,29</p> <p>Russian Federation</p> <p>Telephone: +7 985 192 75 37</p> <p>E-mail: rucis@cytiva.com</p>

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
Импортёр и/или лицо для получения информации об импортёре	<p>ООО "Цитива РУС"</p> <p>109004, г. Москва</p> <p>вн. тер. г. муниципальный округ Таганский</p> <p>ул. Станиславского, д. 21 стр. 5, помещ. I, ком. 24,25,29</p> <p>Российская Федерация</p> <p>Телефон: +7 985 192 75 37</p> <p>Адрес электронной почты: rucis@cytiva.com</p>

Description of symbol on the nameplate

Описание символов на заводской табличке



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

8.3.5 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.

8.3.6 China

Introduction

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

有害物质声明 (DoHS)

Declaration of Hazardous Substances (DoHS)

根据 SJ/T11364-2014《电子电气产品有害物质限制使用要求》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

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。标志中的数字是本产品的环保使用期，表明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，使用本产品不会对环境造成严重污染或对人体健康、造成严重危害的期限。标志单位：年。

环保所声明的环保使用期限，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独立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。到期按产品维修程序更换那些消耗件和零部件，以环保所声明的整个产品的环保使用期限。

本产品在使用寿命结束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.

有害物的名称及含量

Name and Concentration of Hazardous Substances

I品中有害物的名称及含量

Table of Hazardous Substances' Name and Concentration

部件名称 Component name	有害物 Hazardous substance					
	I (Pb)	汞 (Hg)	I (Cd)	六价I (Cr(VI))	多溴I苯 (PBB)	多溴二苯I (PBDE)
29376725	X	0	0	0	0	0

- 0:**

表示I有害物I在I部件所有均I材料中的含量均在 GB/T 26572 I定的限量要求以下。
- X:**

表示I有害物I至少在I部件的某一均I材料中的含量超出 GB/T 26572 I定的限量要求。
- 此表所列数据II布I所能I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.

8.3.7 South Korea

Introduction

This section describes the regulatory information to comply with the Korean technical regulations.

Compliance statement



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 방송통신기자재)

이 기기는 업무용 환경에서 사용할 목적으로 적합성평가를 받은 기기

로서 가정용 환경에서 사용하는 경우 전파간섭의 우려가 있습니다.

8.3.8 General regulatory statements

Introduction

This section shows regulatory statements that are applicable to more than one geographical region.

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.

8.4 Health and Safety Declaration Form

Product return or servicing



Health & Safety Declaration Form for Product Return or Servicing

Return authorization number:		<i>and/or</i> 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:	
<input type="radio"/>	<input type="radio"/>	Radioactivity (specify)	
<input type="radio"/>	<input type="radio"/>	Infectious or hazardous biological substances (specify)	
<input type="radio"/>	<input type="radio"/>	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:		<input type="checkbox"/>	Water
		<input type="checkbox"/>	Ethanol
		<input type="checkbox"/>	None, empty
		<input type="checkbox"/>	Argon, Helium, Nitrogen
		<input type="checkbox"/>	Liquid Nitrogen
		<input type="checkbox"/>	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:			

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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 these 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](https://www.cytiva.com/contact).
28980027 AD 04/2020

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

On site service



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.
<input type="radio"/>	<input type="radio"/>	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.
<input type="radio"/>	<input type="radio"/>	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.
<input type="radio"/>	<input type="radio"/>	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.
<input type="radio"/>	<input type="radio"/>	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:		

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