NanoAssemblr™ Ignite™ and Ignite+™

Operating Instructions

Original instructions

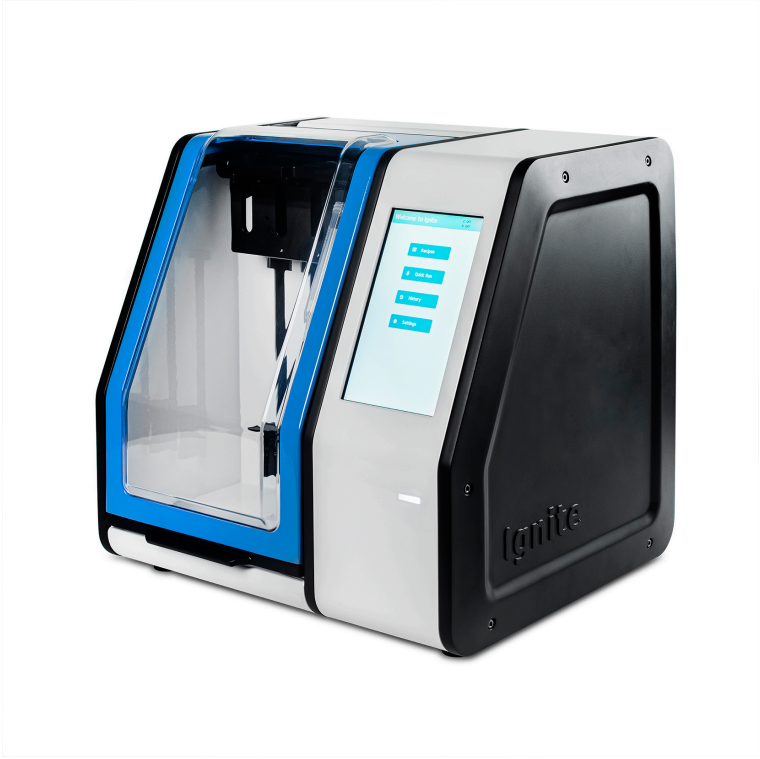

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Table of Contents

1 Introduction

About this chapter

This chapter contains information about this manual and associated user documentation, important user information and intended use of the product.

In this chapter

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 install, operate, or perform maintenance on the product in any other way than described in the user documentation. If you do, you can be exposed or expose others to hazards that can lead to personal injury and you can cause damage to the equipment.

Intended use of the product

NanoAssemblr™ Ignite™ and NanoAssemblr Ignite+™ are intended for the production of nanoparticle formulations for research purposes. The products are intended to be used by trained laboratory staff members in research laboratories within academia and industry.

While the functionality of the two products is the same, the Ignite+ instrument can formulate volumes and flow rates larger than the Ignite instrument.

The products are intended for research and further manufacturing use only, and must not be used in any clinical procedures, or for diagnostic purposes.

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 is valid for the NanoAssemblr Ignite and Ignite+ systems, and covers the Ignite and Ignite+ instruments, embedded software, and accessories.

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 Ignite

The user documentation is listed in the table below.

Translations of the *Operating Instructions* are provided on the web.

Documentation	Main contents
Ignite and Ignite+ Operating Instructions (NIN1134 Rev 6) (this document)	Instructions needed to prepare and operate Ignite in a correct and safe way. System overview, site requirements, and instructions for moving the system within the same building. Instructions for basic maintenance and troubleshooting.

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

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

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. There are also context related precautions, which are written in their respective chapters.

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, or
- damage caused by dropping the product

WARNING

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

WARNING

Access to power switch and power cord. The power switch must always be easy to access. The power cord must always be easy to disconnect.

WARNING

Hazardous substances and biological agents. When using hazardous chemical or biological agents, take all suitable protective measures, such as wearing protective clothing, glasses and gloves resistant to the substances used. Follow local and national regulations for safe operation and maintenance of this product.

Flammable liquids and explosive environment

WARNING

Some of the chemicals used with the system can be flammable under certain conditions. Make sure to use chemicals only under conditions where they are not flammable. Refer to local and/or national classifications of flammable liquids.

WARNING

Explosion hazard: Risk assessment. When using the instrument with flammable liquids, perform a risk assessment for any risks due to the process or process environment. Implement the risk reduction measures needed, including use of personal protective equipment to reduce the risk of electric shock, fire and personal injury.

To be considered when performing the risk assessment:

- All personnel involved in operating, maintaining and servicing the system must have proper knowledge of the local regulations in environments where there is an explosion hazard.
- Risk of liquid spills. Prepare procedures for handling spills of hazardous chemicals in a safe and efficient manner.
- Risk of fire. Do not use flammable liquids with an auto ignition temperature of less than 250°C with the instrument. Remove any external ignition sources or open flames in the vicinity of the instrument.
- Risk of fire. Static discharge from the operator is a potential ignition source. The instrument can be wiped down with a damp cloth to avoid static buildup that can occur in dry ambient conditions.
- Risk of fire. Depending on the input reagents, the collected waste and formulation liquids might be flammable. When formulation is complete, remove the collection vessels in a timely manner and handle the liquids appropriately.

WARNING

Explosion hazard. The product is not approved for use in a potentially explosive atmosphere. The product does not fulfill the requirements of the ATEX Directive.

WARNING

Explosion hazard. Do not turn on the main power switch of the instrument if there are flammable liquids or vapors in the immediate surroundings.

WARNING

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

2.2 Labels and symbols

Introduction

This section describes the nameplate, labels, and other safety and regulatory labels and symbols.

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
⎓	Electrical rating: Voltage (VDC)
Electrical rating	Voltage (VDC), Current (A), Maximum power (W)
Manufac-turing date	Month (MM) and Year (YYYY) of manufacture
SN	Serial number of the instrument

Other labels

The following labels are present on the Ignite or Ignite+ instrument:

Label	Description
	**Warning!** Risk of danger. Consult the user documentation. Proceed with caution.
	**Warning!** Hot surface. Do not touch.
	**Warning!** Crush hazard. Keep hands clear from moving parts to avoid pinch injuries.

Label	Description
	**Warning!** Flammable material.[1] Materials used can be highly flammable when subject to heat.
	**Warning!** Biological hazard.[1] Materials used can be biological hazards.

[1] Indicated hazards are dependent on the materials selected by the user. Refer to SDS and take appropriate precautions for the materials used.

2.3 Emergency procedures

Introduction

This section describes how to shut down NanoAssemblr Ignite or Ignite+ instrument in an emergency situation, and the result in the event of power failure.

The section also describes the procedure for restarting the instrument.

Emergency shutdown

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

Step	Action
1	Tap ***STOP*** on the user interface, or open the lid. *Result:* All run activities are stopped.
2	Press the power switch to the **O** position to completely turn off power to the instrument.
	
3	Unplug the power cord from the wall socket.

Power failure

The following table describes the consequences of a power failure.

Power failure to...	will result in...
Ignite or Ignite+ instrument	• The run is interrupted immediately and the instrument stops formulating. ***Note:*** *The fluid already dispensed can be collected and saved.* • If heating was used, the power to the heaters is cut, but the surfaces remain hot for some time. **CAUTION** **Hot surface.** Avoid direct contact with the heating block and the top surface of the rotating block during or after heating. Contact with hot surfaces during or directly after a procedure in which the heaters are on can cause burns. • The run has the status ***INCOMPLETE*** in the ***History*** menu.

Restart after emergency shutdown or power failure

Before restarting the instrument, make sure the power switch on the back of the instrument is set to the **O** position. Follow the steps below to restart the instrument:

Step	Action
1	If necessary, plug in the power cord to the wall socket.
2	Press the power switch to the **I** position to restart the instrument. *Result:* Upon restart, all of the system components return to their home positions.
3	Remove any syringes or collection tubes.

The instrument is ready to start a new formulation.

3 System description

About this chapter

This chapter gives an overview of Ignite, and a brief description of its function and the software.

In this chapter

3.1 System overview

Overview of Ignite and Ignite+ systems

The Ignite and Ignite+ systems include the instrument, accessories, and single-use cartridges. The systems are operated and controlled from the touchscreen on the instrument.

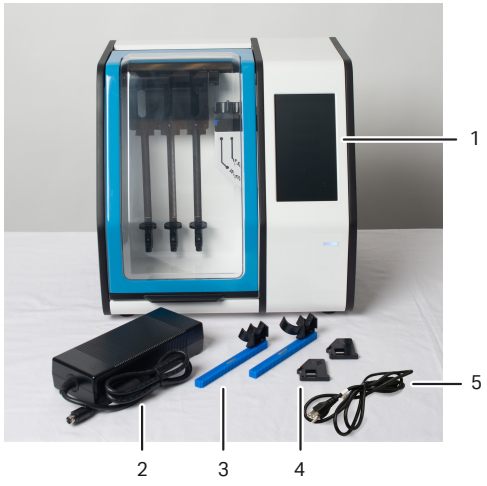
The Ignite and Ignite+ systems use NxGen™ microfluidic mixing cartridges to create reproducible, homogenous, and fast mixing conditions that enable the production of high-quality nanoparticle formulations. The optional heating function facilitates formulation at temperatures above the phase transition temperature of some materials, and enables increased solubility of compounds.

The Ignite and Ignite+ systems differ in the available ranges for volume and flow rate parameters as described in *Section 5.1.2 Mixing parameters, on page 59*.

Illustration of the system

The illustrations below show the Ignite and Ignite+ instruments and the accessories delivered with the system.

Ignite



Ignite+

Part	Description
1	Main instrument
2	Power supply
3	Sample arms[1]

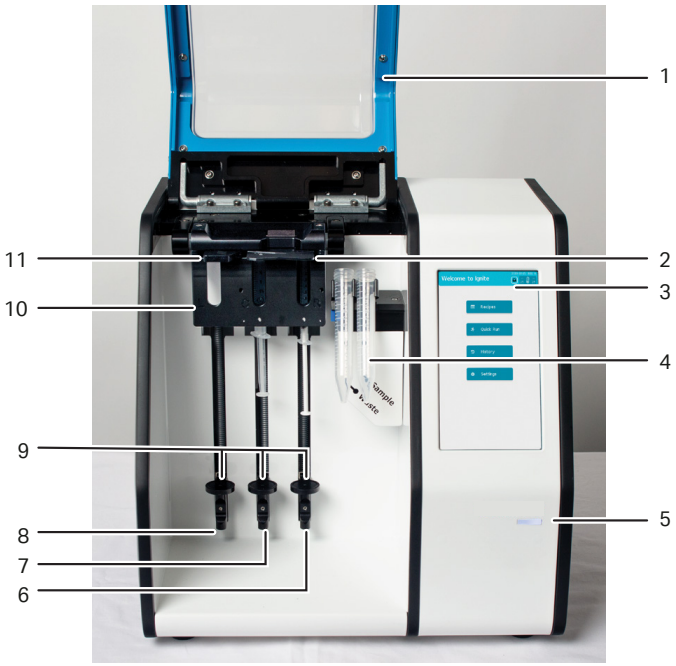
Part	Description
4	Cartridge adapters
5	Power cord

[1] Ignite: Two black sample arms; Ignite+: Three grey sample arms

3.2 Instrument

Illustration of the instrument

The illustration below shows the locations and gives descriptions of the components on the instrument. The rotating block is in the default position, rotated down.



Part	Name	Description
1	Lid	Main instrument lid that must be closed during formulation.
2	Cartridge	Single-use cartridges with built-in mixer geometries to combine reagents and deliver the mixed fluid to the collection tubes.
3	User interface	A user interface with touch screen display.
4	Collection tubes	Tubes for collecting the sample and the waste from the formulation.
5	Status indicator	When lit, the instrument is powered on.
6	Right (**R**) pusher	Syringe pushers press the syringe pistons at independently controlled rates.
7	Center (**C**) pusher	
8	Left (**L**) pusher	

Part	Name	Description
9	Paddles	Paddle attachments to the syringe pushers come in contact with the syringe pistons .
10	Rotating block	A block where the cartridge, syringes, and optional heating block are connected to the instrument. The block rotates from the default (down) position into the loading (up) position.
11	Cartridge adapter	Cartridge adapters that are required for use with two-inlet cartridges.

Detailed view of the rotating block

The illustration below shows a detailed view of the locations of the components on the instrument. The rotating block is in the loading position, rotated up.

Part	Name	Description
1	Cartridge	See above section
2	Cartridge adapter	See above section
3	Sample arm	Sample arms with different sized holders to hold the collection tubes. ***Note:*** *The sample arms supplied with the system differ between the Ignite and Ignite+ systems.*

Part	Name	Description
4	Heating block	An optional heating block to maintain the temperature of preheated reagents and syringes above the ambient temperature. ***Note:*** *The heating block is not a default part of the system and must be requested and installed separately.*

3.3 Microfluidic cartridges

Introduction

This sections describes the microfluidic cartridges available for Ignite and Ignite+ systems.

In this section

3.3.1 Introduction

The single-use cartridges have a built-in microfluidic mixer technology that enables mixing of two or three fluids. Two mixer geometries are available for the Ignite and Ignite+ instruments. The table below gives an overview of the cartridge types and their purposes.

Cartridge	Number of inlets	Purpose	Instrument compatibility
NxGen	2	Bench-scale and preclinical formulation up to 20 mL/min (predilution)	Ignite Ignite+
NxGen Dilution	3	Bench-scale and preclinical formulation up to 20 mL/min (predilution)	Ignite Ignite+
NxGen 500	2	Clinical development and commercial production from 50 mL/min to 200 mL/min (predilution)	Ignite+
NxGen 500D	3	Clinical development and commercial production from 50 mL/min to 200 mL/min (predilution)	Ignite+

Note: *Recommended shelf life for all cartridges is 1 year.*

3.3.2 Two-inlet cartridges

Introduction

The NxGen cartridge combines reagents from the C and R channels through the mixer and delivers the mixed fluid to the collection tubes.

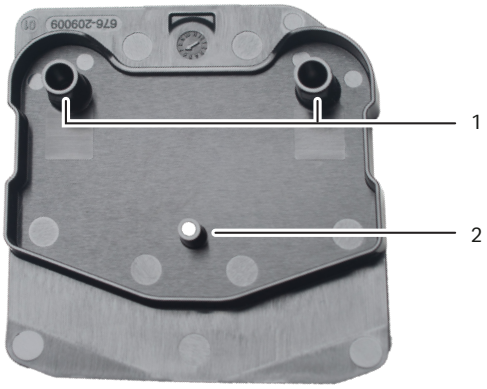
Illustration of two-inlet cartridge front

The illustrations below show the locations and gives brief descriptions of the parts on the front of the cartridge.

Part	Description
1	Cartridge inlets
2	Mixer geometry
3	Cartridge outlet

Illustration of two-inlet cartridge back

The illustration below shows the locations and gives brief descriptions of the parts on the back of the cartridge.



Part	Description
1	Cartridge inlets with Luer fittings to connect to syringes
2	Cartridge outlet

3.3.3 Three-inlet cartridges

Introduction

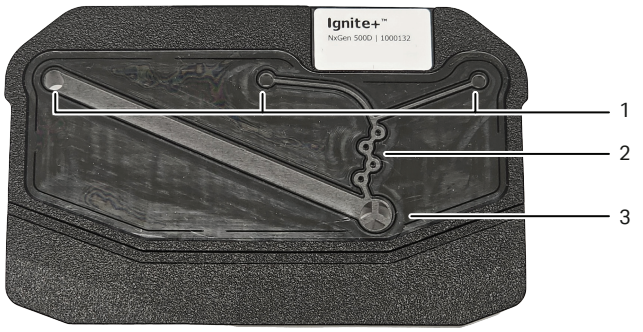
NxGen Dilution and NxGen 500D cartridges have three inlets to enable in-channel dilution. The cartridges combine reagents from the C and R channels through the mixer, and introduce the reagent from the L channel in the T-junction at the output of the mixer.

Illustration of three-inlet cartridge front

The illustrations below show the locations and gives brief descriptions of the parts on the front of each cartridge.

NxGen Dilution

NxGen 500D



Part	Description
1	Cartridge inlets

Part	Description
2	Mixer geometry
3	Cartridge outlet

3.4 User interface

Introduction

This section describes the user interface for Ignite and Ignite+ instrument.

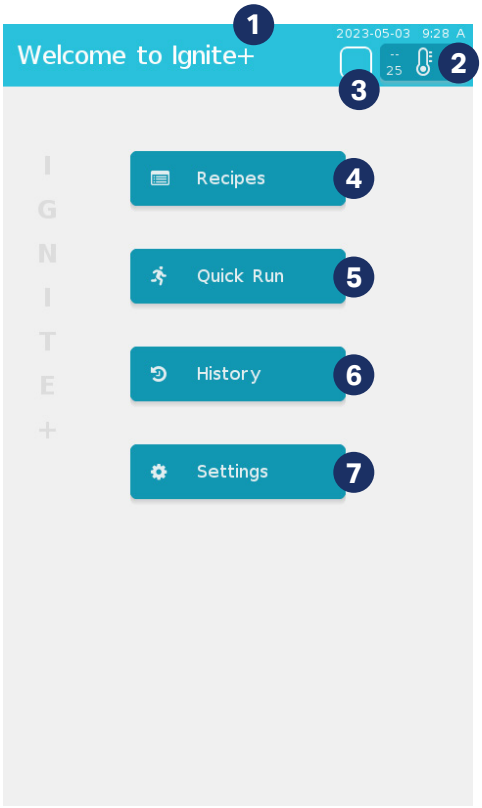
In this section

3.4.1 Main menu

Overview

The operation and user interface is identical for the Ignite and Ignite+ instruments. Both instruments have a touchscreen user interface mounted on the front of the main instrument.

The illustration below shows the main menu on the instrument.



Part	Name	Description
1	Information bar	Includes menu title, and current date and time
2	Heater control icon	Shows the status of the heating system
3	Cartridge indicator	Shows the status of the cartridge in the instrument
4	***Recipes***	Enables user to create, edit, and store formulations providing convenient access to frequently used formulations

Part	Name	Description
5	***Quick Run*** menu	Enables user to directly run formulations, such as one-off formulations or new formulations that are being refined
6	***History*** menu	Enables user to access a list of the last 800 formulations run on the instrument, including ***Quick Run*** and ***Recipe*** formulations
7	***Settings*** menu	Enables user to adjust the date and time, and syringe

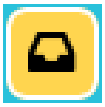
Heater control icon

The following table gives examples of how to interpret the information shown in the heater control icon.

Heater control icon	Description	Meaning
	No setpoints are displayed, no red border, and background is blue	Both heaters are off. The temperatures of the heaters are below 45°C.
	Red border with blue background	One or both heaters are on, but the temperatures of the heaters are below 45°C. In this example, both heaters are on, with a setpoint of 65°C.
	Red border with red background	The red background indicates that the temperature of one or both heaters is above 45°C.
	Orange background with red border	The orange background indicates that the temperature is within 5°C of the setpoint.
	Red background with no border	The red border is not present because both heaters are off. The red background remains until both heaters are below 45°C.

Cartridge indicator states

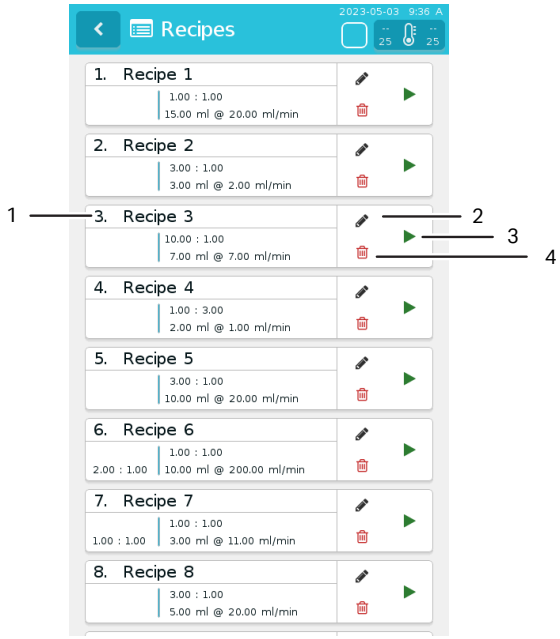
The following table gives the meaning of each cartridge indicator symbol.

Cartridge symbol	Meaning
	No cartridge detected
	Cartridge detected
	Cartridge is unacceptable for the current run for one of the following reasons: • The cartridge is the wrong type for the current run • The cartridge has been used previously ***Note:*** *This state is only displayed when viewing or editing parameters for a run*
	Cartridge is acceptable for the current run

3.4.2 *Recipes* menu

The illustration below shows the ***Recipes*** menu.

Note: *Unavailable buttons appear dimmed on the user interface. It is not possible to tap the unavailable buttons.*



Part	Description	Function
1	Recipe name	User input recipe name and summary or key parameters
2	Edit button	Opens the parameters menu for the user to edit the parameters of the recipe
3	Run button	Runs the selected recipe
4	Delete button	Deletes the selected recipe

3.4.3 *Quick run*

The user can directly enter run parameters on the ***Quick run*** screen. See *Quick run, on page 88* for instructions on how to initiate a run with ***Quick run***.

3.4.4 *History* menu

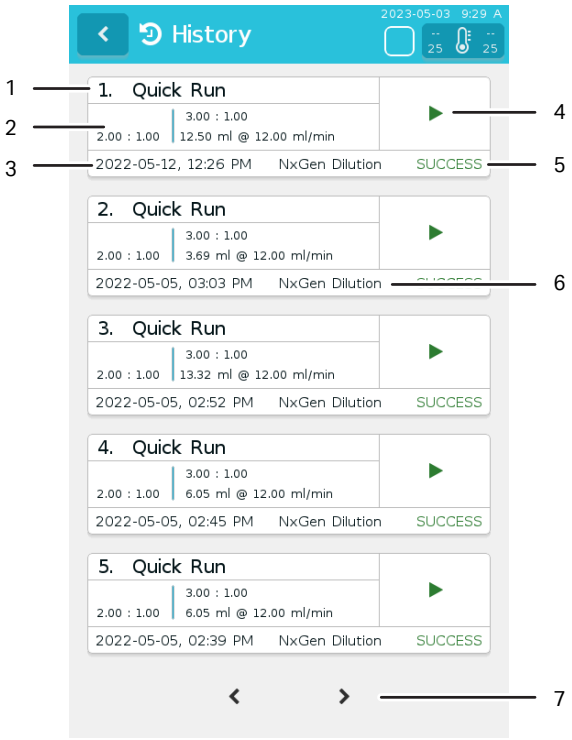
The ***History*** menu shows a list of both ***Quick Run*** and ***Recipe*** formulations, ordered from newest to oldest.

Each history entry shows:

- Recipe name
- Time and date of the run
- Run parameters
- Result

The parameters found in a history entry can be re-run as a new formulation by tapping the run button to the right of the entry.

The illustration below shows the ***History*** menu.

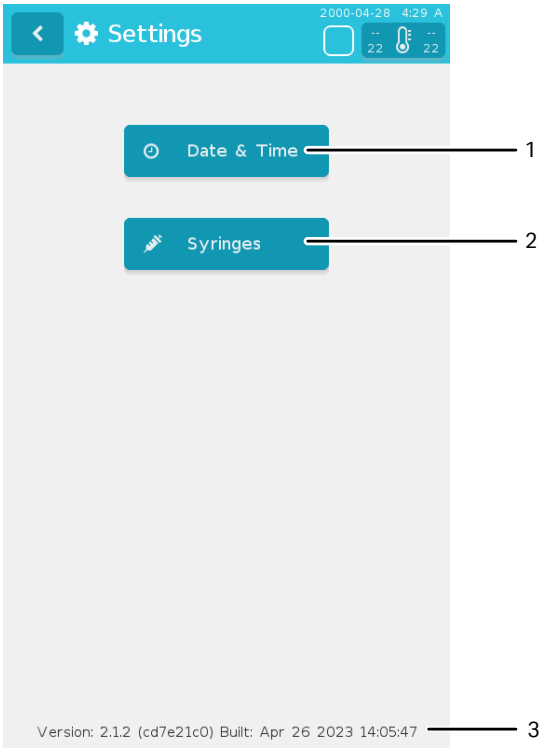


Part	Description	Function
1	Quick run or recipe name	Shows Quick run or user-input recipe name
2	Run parameters	Shows key run parameters
3	Time and date of run	Shows time and date the run was performed

Part	Description	Function
4	Run button	Starts a new run with the same parameters as the selected run
5	Result	Shows the result of the run: • ***SUCCESS***: The run succeeded • ***INCOMPLETE***: The run was interrupted by the user pressing ***STOP***, by an error detected throughout the run, or by a power failure to the instrument.
6	Cartridge type	Shows the cartridge type used during the run
7	Navigation arrows	Navigates between pages

3.4.5 *Settings* menu

The illustration below shows the ***Settings*** menu.



Part	Description	Function
1	Date & Time	Opens the menu to change the date and time
2	Syringes	Shows a list of compatible syringe brands and sizes.
3	Software version	Shows the current software version ***Note:*** *Cytiva might ask for the software version when providing technical support.*

3.5 Accessories

Introduction

This section describes the accessories available for Ignite and Ignite+ systems.

In this section

3.5.1 Heating insert

Introduction

The Ignite and Ignite+ systems can be operated with metal sleeves called heating inserts, which are placed around the syringe. The heating inserts ensure good thermal contact between the syringe heaters of the instrument and differently sized syringes.

Heating inserts are specific to the instrument. See *Section 9.5 Ordering information, on page 130* for more information. The image below shows an Ignite heating insert.

Ignite heating insert compatibility

Each Ignite heating insert is labeled with a size. The table below shows which heating insert size is appropriate for each compatible syringe manufacturer.

Syringe size	Heating insert size							
	BD	B Braun Injekt	B Braun Omnifix	Terumo	Shinva Ande	KDL	WEGO	KOVAX
1 mL	1 mL	1 mL	1 mL	1 mL	3 mL	1 mL	X	3 mL
2 mL	X	X	X	X	3 mL	3 mL	3 mL	X
2.5 mL	X	X	X	X	X	X	X	X
3 mL	3 mL	X	3 mL - O	3 mL	3 mL	X	X	X
5 mL	5 mL	5 mL	5 mL	5 mL - T	5 mL	5 mL	5 mL	X
10 mL	10 mL	10 mL	10 mL	10 mL	10 mL	10 mL	10 mL	X
X: Syringe not supported by Ignite instrument								

Ignite+ heating insert compatibility

Each Ignite+ heating insert is labeled with a size. The table below shows which heating insert size is appropriate for each compatible syringe manufacturer.

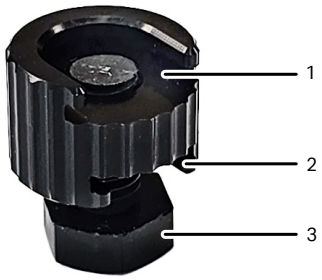
Syringe size	Heating insert size							
	BD	B Braun Injekt	B Braun Omnifix	Terumo	Shinva Ande	KDL	WEGO	KOVAX
1 mL	1 mL	1 mL	1 mL	1 mL	3 mL	1 mL	X	3 mL
2 mL	X	X	X	X	3 mL	3 mL	3 mL	X
2.5 mL	X	X	X	X	X	X	X	X
3 mL	3 mL	X	3 mL - O	3 mL	3 mL	X	X	X
5 mL	5 mL	5 mL	5 mL	5 mL - T	5 mL	5 mL	5 mL	X
10 mL	10 mL	10 mL	10 mL	10 mL	10 mL	10 mL	10 mL	X
20 mL	20 mL	20 mL	20 mL	20 mL	X	X	X	X
30 mL	✓	X	✓	✓	X	X	X	X

X: Syringe not supported by Ignite+ instrument

✓: No insert is needed for the specified syringe

3.5.2 Syringe extenders

Syringe extenders can be used to extend the overall length of certain syringes that are too short to use in the Ignite and Ignite+ systems. To use the syringe extender, the flange of the syringe plunger is inserted into a slot in the syringe extender and the syringe is secured with a fastening screw. The illustrations below shows the parts of a syringe extender.



Part	Description
1	Slot to insert the flange of the syringe plunger
2	Slot to insert the fastening screw
3	Fastening screw to secure the syringe

Syringe extenders must be used with the following syringe manufacturers and sizes:

- B Braun Injekt syringes, 2 mL
- Terumo syringes, 2.5 mL

See *Section 9.5 Ordering information, on page 130* for more information.

4 Installation

About this chapter

This chapter provides required information to enable users and service personnel to unpack, install, move and transport the Ignite or Ignite+ system.

In this chapter

4.1 Site preparation

Introduction

This section describes the site planning and preparation that should be performed before the product is installed.

In this section

4.1.1 Delivery, storage and unpacking

Introduction

This section describes the requirements for receiving the delivery box and storing the instrument before installation.

This section outlines important information that must be considered when handling the transport crate, unpacking the system and moving the system after unpacking.

Two people are recommended to safely unpack and move the instrument, and no special equipment is needed.

When you receive the delivery

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

Delivery box

Ignite and Ignite+ instruments are shipped in a delivery box with the following dimensions and weight:

Contents	Dimensions (W × D × H)	Weight
Ignite or Ignite+ instrument with accessories	51 × 51 × 51 cm (20 × 20 × 20 in)	22 kg (48.5 lb)

Storage requirements

The delivery boxes should be stored at a protected place indoors. The storage place for unopened boxes must meet the following requirements:

Parameter	Allowed range
Ambient temperature, storage	15°C to 35°C
Relative humidity	25% to 65%, non-condensing

Transportation

The following equipment is recommended for handling the delivery boxes:

Equipment	Specifications
Cart for transporting the instrument to the lab	Dimensioned to accommodate the size and weight of the instrument

Unpacking the instrument

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.

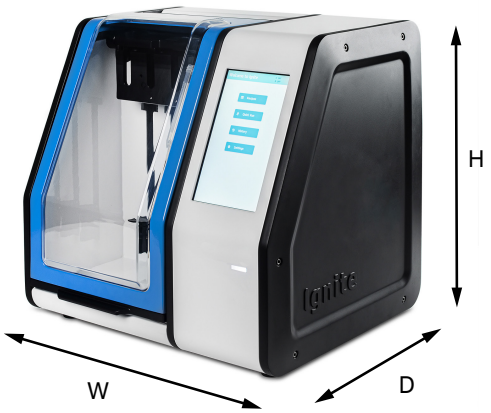
4.1.2 Room requirements

Introduction

This section describes the requirements for the room where the system is placed.

Dimensions and weight

The following illustration shows the dimensions of the Ignite instrument.



Parameter	Value
W	38 cm (15 in)
D	34 cm (13.4 in)
H	38 cm (15 in)
Weight	16 kg (35.3 lb)

Space requirements

WARNING

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

CAUTION

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

The Ignite or Ignite+ can be installed on a standard laboratory bench.

Prepare a clean working area on a stable laboratory bench that complies with the specifications in the following table. There must be sufficient space to turn the instrument on the bench for service access to the rear panel.

Parameter	Specification
Minimum bench area for operating the instrument (W x D x H)	40 x 44 x 73 cm (15.7 x 17.3 x 28.7 in)
Load capacity	Enough to support instrument and any other accessories on the laboratory bench
Inclination of bench surface	Horizontal ±2°

4.1.3 Site environmental requirements

Introduction

This section describes the environmental requirements and conditions for installation of Ignite or Ignite+.

CAUTION

The product is designed for indoor use only.

Environmental requirements

The installation site must comply with the following specifications.

Parameter	Requirement
Allowed location	Indoor use only
Ambient temperature	15°C to 35°C
Relative humidity	25% to 65%, non-condensing
Pressure	0.070 to 0.106 MPa
Altitude	Maximum 2000 m
Pollution degree of the intended environment	Pollution degree 2

Environmental conditions

The following general requirements must be fulfilled:

- The room must have exhaust ventilation.
- Dust in the atmosphere should be kept to a minimum.

Heat output

The heat output data is listed in the table below. The heat output data is valid when the syringe heaters are installed and on.

Component	Heat output
Syringe heaters on the Ignite or Ignite+ instrument	Maximum output per heater: 35 W
Total	Maximum: 70 W

4.1.4 Power requirements

Introduction

This section describes the electrical power requirements for the Ignite or Ignite+ instrument.

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.

Electrical power requirements

The following table specifies the power requirements for the instrument.

Parameter	Requirement
Supply voltage	100 to 240 V~
Supply current	4 A
Output voltage	24 Vdc
Output current	6.3 A
Output power	151 W
Frequency	50/60 Hz
Power outlet type	Grounded mains outlets
Transient overvoltages	Overvoltage category II
Location of sockets	Maximum 2 m from the instrument (due to length of mains cable). Extension cables can be used if required.

Power quality

The mains power supply must be stable and conform to specifications at all times to ensure reliable operation of the instrument. Avoid transient or slow changes in average voltage outside the limits specified above.

4.2 Installing the system

Introduction

This section describes the procedure for installing the Ignite or Ignite+ system.

Safety precautions

WARNING

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

WARNING

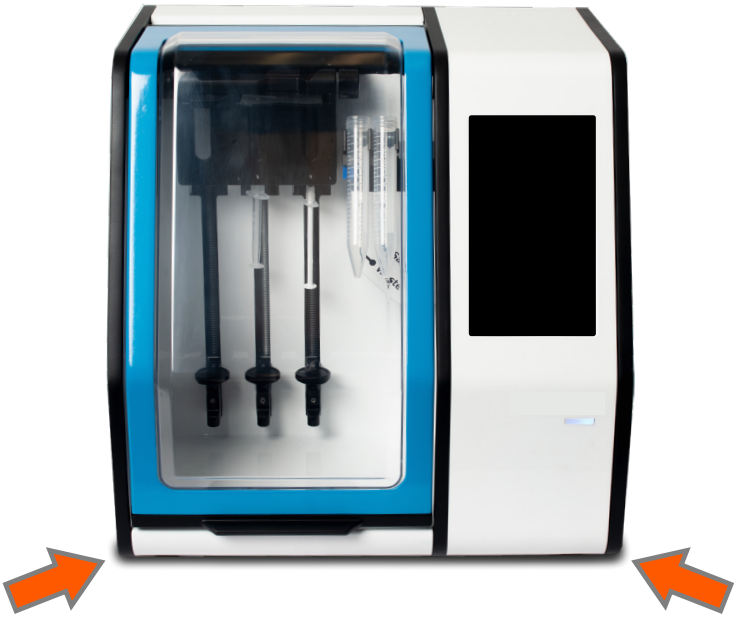
Protective ground. The product must be connected to a grounded power outlet.

WARNING

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

Place the instrument on the bench

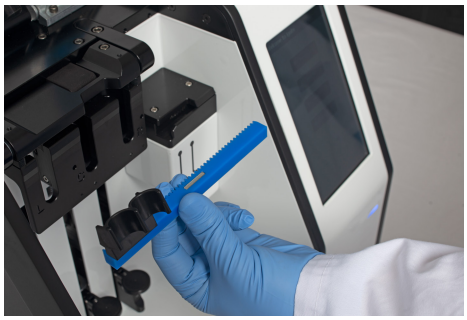
Place the instrument on the bench (see *Space requirements, on page 45* for space requirements). Lift the instrument from the base. It is recommended to use two people to lift the instrument.



Install internal components

Follow the instructions below to unpack and install the components of the instrument under the lid.

Step	Action
1	Lift the lid of the instrument.
2	Remove the protective insulation from the pushers.
3	Make sure that the paddles attached to the pushers are in the horizontal orientation.

Step	Action
4	Hold the applicable sample arm with the tube holders on the left top side. 
5	Align the body of the sample arm with the holder on the instrument. 
6	Push the sample arm into the holder horizontally. 

4.3 Moving the system

WARNING

When moving the instrument for maintenance or other purposes, disconnect all cables from wall sockets and separate equipment so that the cables do not pull on the instrument or equipment.

When moving the Ignite or Ignite+ system within and between sites, remove all cartridges, syringes, or connection tubes. It is recommended to use two people to move the instrument.

For transport between laboratories, use a cart dimensioned to accommodate the size and weight of the instrument. For transport over longer distances, pack the instrument securely in a protective box. Use the original packing material if possible.

Contact Cytiva for information on moving the system over longer distances.

4.4 Electrical connections

Introduction

This section shows the electrical connections that must be made to the product. If the product is moved within the lab or to another building, the product has to be reconnected to electrical power and network (optional).

Safety precautions

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.

Connect power to the instrument

Follow the instructions below to connect power to the NanoAssemblr Ignite or Ignite+ instrument.

WARNING

Protective ground. To reduce the risk of electric shock, this equipment must always be connected to a grounded power outlet.

Step	Action
1	Connect the power supply to the port at the rear of the NanoAssemblr Ignite or Ignite+ instrument.

Note:
To remove the power supply from the instrument, slide the sheath of the connector backwards while pulling the connector out.

2	Connect the power supply to the power cord.
3	Connect the power cord to a grounded wall outlet with a voltage according to the site requirements in *Electrical power requirements, on page 48*.

5 Preparation

About this chapter

This chapter gives instructions on how to set up a run with the Ignite or Ignite+ system.

In this chapter

5.1 Parameters

Introduction

Run parameters may be entered and saved in a recipe from the ***Recipes*** screen, or entered on the ***Quick run*** screen prior to starting a run.

In this section

5.1.1 Syringe selection

Introduction

It is important to correctly set the size and brand of syringe in the parameters to achieve accurate mixing results. Flow rate control is based on the syringe dimensions that are included in the software.

IMPORTANT
The syringe size and manufacturer chosen in the parameters must match the syringe used during a run. Using a different syringe than the one selected in the parameters impacts particle characteristics due to the resulting incorrect flow rates and flow ratios.

Syringe sizes

When creating a recipe or starting a quick run, it is possible to select the syringe size and type by selecting from a drop-down menu.

Tip: *Use the smallest syringe that can accommodate the dispensed volume, because smaller syringes usually reach the target flow rate faster and require a smaller volume of start waste.*

The table below shows the range or values available for each syringe channel for the different instruments.

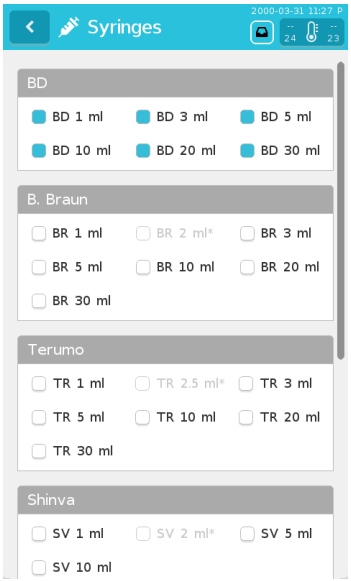
Instrument	Syringe size		
	L syringe	C syringe	R syringe
Ignite	Up to 30 mL	Up to 10 mL	Up to 10 mL
Ignite+	Up to 30 mL	Up to 30 mL	Up to 30 mL

Update available syringe types

The available syringe types are shown in a drop down menu when editing run parameters. Follow the instructions below to update which syringes are shown in the parameter settings during a ***Quick Run*** or ***Recipe*** procedure.

Step	Action
1	From the main menu, tap ***Settings***.
2	Tap ***Syringes***. *Result:* A list of compatible syringe brands and sizes are displayed. The syringes are grouped by brand. Each syringe is identified by a two-letter code for the brand and the syringe volume.

Step	Action



Note:
Syringe types that are not compatible with the heater appear dimmed when the heating insert is present.

3 Tap the empty box next to a syringe name to add the syringe to the list of available syringes.

4 Tap the blue box next to a syringe name to remove the syringe type from the list of available syringes.

5 Tap the back arrow at the top left of the screen to apply the settings.

5.1.2 Mixing parameters

Introduction

Mixing parameters can influence characteristics such as particle size and polydispersity index (PDI). Particle size and PDI are also influenced by the chemistry, including the choice of carrier, choice of solvents and buffers, and concentrations of reagents.

Mixing parameters include the ***Flow rate ratio***, the ***Total volume*** and the ***Total flow rate*** . NxGen Dilution and NxGen 500D formulations also require a ***Dilution ratio***.

The total flow rate and the flow rate ratio are the most influential mixing parameters to tune for achieving optimal particles for a given application. For more information on parameter combinations, including detailed application notes, papers, webinars, and other resources, visit cytiva.com.

Tip: *Adjust the total flow rate and the flow rate ratio and then evaluate the formulation composition to determine the optimal parameter combination.*

Flow rate ratio

The flow rate ratio is the ratio between the volumes of fluids from the C and R syringes. For example, in a nanoprecipitation reaction, the flow rate ratio specifies the ratio between the polar aqueous phase and the organic phase. Increasing the proportion of the aqueous phase increases the magnitude of the polarity change experienced by the molecules. In many formulations, an increase in the aqueous phase leads to smaller particles.

The table below gives the range of values that can be input for the parameter ***Flow rate ratio***.

Instrument	*Flow rate ratio*
Ignite	1:1 to 10:1
Ignite+	

Total volume

The value of the parameter ***Total volume*** gives the amount of liquid that is formulated before dilution during the procedure. The table below gives the range of possible values.

Instrument	*Total volume*
Ignite	1 mL to 20 mL
Ignite+	1 mL to 60 mL

Total flow rate

The total flow rate specifies the sum of the flow rates of the C and R channels, before the optional dilution. A higher total flow rate value results in faster mixing. In most nanoprecipitation reactions, a higher total flow rate results in smaller particles up to a limit determined by the chemistry.

The table below gives the range of values that can be input for the parameter ***Total flow rate***.

Instrument	*Total flow rate*
Ignite	0.1 to 20 mL/min
Ignite+	0.1 to 200 mL/min

Flow rate limitations on Ignite+

Due to the physical limitations of syringes, certain flow rates within the Ignite+ parameter range are restricted on smaller syringes. The table below gives the maximum flow rate for a single channel for each compatible syringe by supplier.

Syringe size	Maximum flow rate for a single channel (mL/min)							
	BD	B Braun Injekt	B Braun Omnifix	Terumo	Shinva Ande	KDL	WEGO	KOVAX
1 mL	20.8	20.8	20.8	20.8	20.8	20.6	-	20.4
2 mL	-	88.7	-	-	75.6	75.2	76.1	-
2.5 mL	-	-	-	76.3	-	-	-	-
3 mL	69.5	-	89.6	75.5	-	-	-	-
5 mL	135	147	146	159	140	142	148	-
10 mL	196	238	238	235	206	205	209	-
20 mL	342	381	379	385	-	-	-	-
30 mL	435		435	435	-	-	-	-

Note: *The chosen flow rate ratio impacts the required flow rate per channel for a given total flow rate. For example, to perform a run with the following parameters,*

- *200 mL/min total flow rate,*
- *3:1 flow rate ratio ,*
- *and BD syringes,*

the minimum syringe sizes that can be used are:

- *one 10 mL syringe (at 150 mL/min),*
- *and one 3 mL syringe (at 50 mL/min).*

Dilution ratio

The dilution ratio is the ratio between the volume of the dilution solution (L channel) and the combined volume of the reagents from the C and R channels.

The value of the parameter ***Dilution ratio*** can be up to 10:1 for both instruments.

The limitations on the flow rate for each channel can reduce the maximum dilution ratio for a specific recipe. The table below gives the maximum flow rate for the dilution channel for each instrument. The dilution flow rate is calculated automatically by the instrument based on the other parameter settings.

Instrument	Dilution flow rate
Ignite	0.1 to 48 mL/min
Ignite+	0.1 to 435 mL/min

5.1.3 Waste parameters

Introduction

The instrument can collect fluid at the beginning and the end of a procedure to decrease the variation in the particle characteristics of the output.

At the beginning of a run, the fluid flow rate can vary from the target as the paddles accelerate to full speed. Before steady-state flow has been reached, there can be off-target mixing between the reagents. The amount of start waste to collect depends on the following factors:

- **The syringe size**. Syringes can deform under the forces applied by the instrument. Larger syringes deform more than smaller syringes and therefore take longer to reach the intended flow rate.
- **The target flow rate**. Higher flow rates result in a higher volume of fluid output as the system reaches its intended flow rate
- **The sensitivity of the formulation to flow rate parameters**. Some formulations are more sensitive than others to deviations in flow rate.
- **The final application for the particles**. Observed differences in size can affect biological endpoints.

The parameter ***Start waste*** defines the volume of fluid to collect in the waste collection tube at the beginning of the run.

The parameter ***End waste*** defines the volume of fluid to collect in the waste collection tube at the end of the run.

Start waste recommendations for NxGen and NxGen Dilution Cartridges

The value for the parameter ***Start waste*** can be between 0 mL and the value of ***Total volume***.

The recommended values for the parameter ***Start waste*** can be calculated by summing the recommended start waste values for specific syringe sizes.

Note: *The following recommendations suggest collecting a larger amount of waste to ensure the most uniform population of particles. If it is desirable to collect less waste, optimize the parameter values by systematically collecting less waste and testing each result. Contact us for further help with parameter optimization. See* *Contact information for support, on page 119**.*

If using two different sized syringes in the C and R channels, add the values listed for the smaller syringe size and the larger syringe. If using dilution, add the value from the column *Dilution syringe*. If using same size syringes for both channels, skip to the second table for calculation recommendations.

Syringe size (mL)	Values used to calculate *Start waste* for different sized syringes (mL)		
	Smaller syringe	Larger syringe	Dilution syringe
1	0.10	N/A	0.20
3	0.15	0.35	0.25
5	0.20	0.50	0.35
10	0.30	0.80	0.50
20	-	-	0.65
30	-	-	0.65

If the syringes for the C and R channels are the same size, use the start waste value listed in the table below. If using dilution, add the value from the column *Dilution syringe*. If using same size syringes for both channels, skip to the second table for calculation recommendations.

Syringe size (mL)	Values used to calculate *Start waste* for same sized syringes (mL)	
	Same size syringes	Dilution syringe
1	0.3	0.20
3	0.50	0.25
5	0.70	0.35
10	1.10	0.50
20	-	0.65
30	-	0.65

Start waste recommendations for NxGen 500 and NxGen 500D Cartridges

The value for the parameter ***Start waste*** can be between 0 mL and the value of ***Total volume***.

The recommended values for the parameter ***Start waste*** can be calculated by summing the recommended start waste values for specific syringe sizes.

Note: *The following recommendations suggest collecting a larger amount of waste to ensure the most uniform population of particles. If it is desirable to collect less waste, optimize the parameter values by systematically collecting less waste and testing each result. Contact us for further help with parameter optimization. See* *Contact information for support, on page 119**.*

If using two different sized syringes in the C and R channels, add the values listed for the smaller syringe size and the larger syringe. If using dilution, add the value from the column *Dilution syringe*. If using same size syringes for both channels, skip to the second table for calculation recommendations.

Syringe size (mL)	Values used to calculate *Start waste* for different sized syringes (mL)		
	Smaller syringe	Larger syringe	Dilution syringe
1	0.05	N/A	0.20
3	0.10	0.20	0.25
5	0.15	0.30	0.35
10	0.30	0.50	0.50
20	0.40	1.40	0.65
30	0.50	2.35	0.65

If the syringes for the C and R channels are the same size, use the start waste value listed in the table below. If using dilution, add the value from the column *Dilution syringe*. If using same size syringes for both channels, skip to the second table for calculation recommendations.

Syringe size (mL)	Values used to calculate *Start waste* for same sized syringes (mL)	
	Same size syringes	Dilution syringe
1	0.20	0.20
3	0.30	0.25
5	0.50	0.35
10	0.80	0.50
20	1.60	0.65
30	2.70	0.65

Start waste example calculations

The following examples explain how to calculate the value of the ***Start waste*** parameter using the Ignite start waste table.

Example 1: Two same sized syringes with dilution

For a formulation with two 3 mL syringes and a 5 mL dilution syringe, the ***Start waste*** value is calculated as follows:

Two same size syringes, 3 mL:	0.50
Dilution syringe, 5 mL:	+ 0.35
Recommended start waste:	= 0.85

Syringe size (mL)	Values used to calculate *Start waste* for same sized syringes (mL)	
	Same size syringes	Dilution syringe
1	0.3	0.20
3	**0.50**	0.25
5	0.70	**0.35**
10	1.10	0.50
20	-	0.65
30	-	0.65

Example 2: Two different sized syringes without dilution

For a formulation with a 3 mL and a 5 mL syringe, the ***Start waste*** value is calculated as follows:

Smaller syringe, 3 mL:	0.15
Larger syringe, 5 mL:	+ 0.50
Recommended start waste:	= 0.65

Syringe size (mL)	Values used to calculate *Start waste* for different sized syringes (mL)		
	Smaller syringe	Larger syringe	Dilution syringe
1	0.10	N/A	0.20
3	**0.15**	0.35	0.25
5	0.20	**0.50**	0.35
10	0.30	0.80	0.50
20	-	-	0.65
30	-	-	0.65

End waste

The end of a run does not have the same degree of non-steady-state flow conditions as the start. Therefore, the value of the parameter ***End waste*** is much less susceptible to syringe size or target flow rate dependencies.

A value of 0.05 mL is recommended for the parameter ***End waste*** for all syringe combinations and flow rates.

Note: *For some formulations, no collection of end waste is required. In this case, the value of* ***End waste*** *can be set to 0 mL.*

5.1.4 Parameter validation

After all run parameters have been entered, the parameter combination is validated. If run parameters are missing or outside the operational limits of the instrument, an error message is displayed in red at the bottom of the screen.

Examples of incompatible parameters include:

- The combination of ***Total flow rate***, ***Total volume***, and ***Flow rate ratio*** causes the a flow rate for a single channel to exceed the operational limit.
- The combination of ***Total volume*** and ***Flow rate ratio*** causes the dispense volume for a single syringe to be larger than the syringe size.
- The ***Total flow rate*** is higher than the maximum operational flow rate.

For some validation errors, the problematic parameter is highlighted in red. For validation errors that are the result of calculated values for a single channel, no parameters is highlighted, as there is more than one parameter value that can be adjusted to fix the error.

When resolving validation errors, use the volume and flow rate calculations displayed for each channel under the syringe drop-down lists.

If errors are present, adjust the run parameters to within the flow rate and volume limitations. See *Section 5.1.2 Mixing parameters, on page 59* for the range of acceptable flow rates and volumes.

5.2 Recipes

Introduction

Recipes are used to store frequently used run parameters, or to retain run parameters when multiple users are sharing a single instrument.

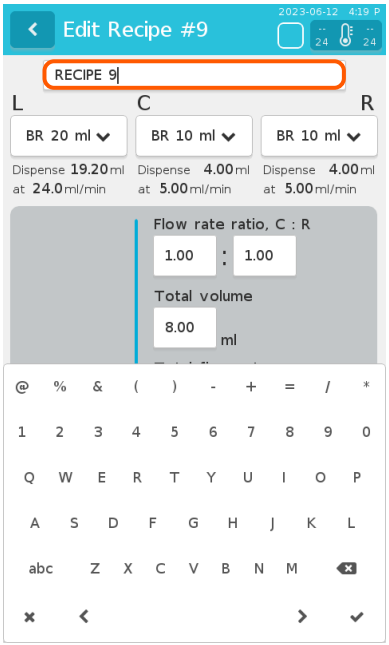
Recipes can be named and are stored in one of ten numbered slots in the ***Recipes*** menu. Any slot can be used, and slots can also be left empty.

Create or edit a recipe

Follow the instructions below to create or edit a recipe.

Step	Action
1	From the main menu, tap ***Recipes***.
2	Tap the edit button next to the recipe. *Result:* The recipe parameters are shown.

Step	Action
3	Tap the recipe name field to open the on-screen keyboard and enter the recipe name.



Note:
To close the on-screen keyboard, tap the check mark at the bottom right of the on-screen keyboard or tap anywhere on the screen.

4 Enter the parameters as follows. See *Section 5.1 Parameters, on page 56* for parameter ranges and recommendations.

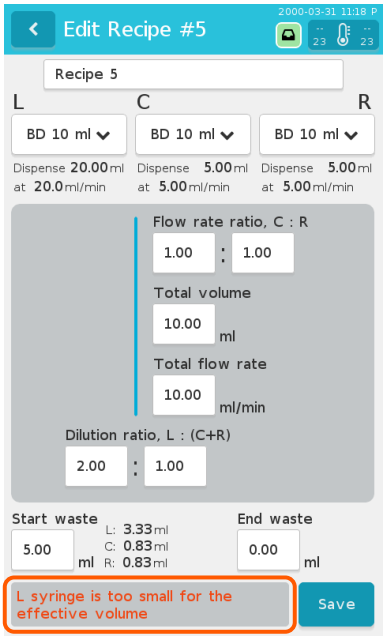
a. Tap the arrows under ***L***, ***C***, and ***R*** to open a drop down list and select the syringe sizes.

   Note:
   *The **L** field is only required for recipes that use a NxGen Dilution or NxGen500D cartridge. For all other cartridges, leave this field blank.*

b. Tap each field to open the on-screen keyboard and enter the parameter value with up to two decimal places.

   Note:
   *Enter values for **Dilution ratio, L : (C+R)** only for recipes that use a NxGen Dilution or NxGen500D cartridge. For all other cartridges, leave this field blank.*

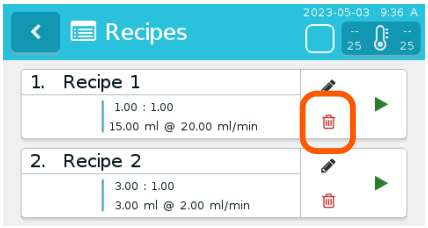
Step	Action
	Result: After all parameters have been entered, the combination of parameters is validated. The calculated volumes and flow rates for each channel are displayed under the syringe drop-down lists. The calculated volume of start waste for each syringe is displayed to the right of the ***Start waste*** field.
5	Correct any errors identified in red at the bottom of the screen. See *Section 5.1.4 Parameter validation, on page 67* for details.
6	Tap ***Save*** in the bottom right corner of the screen. *Result:* The screen returns to the ***Recipes*** menu.



Delete a recipe

Follow the instructions below to delete a recipe.

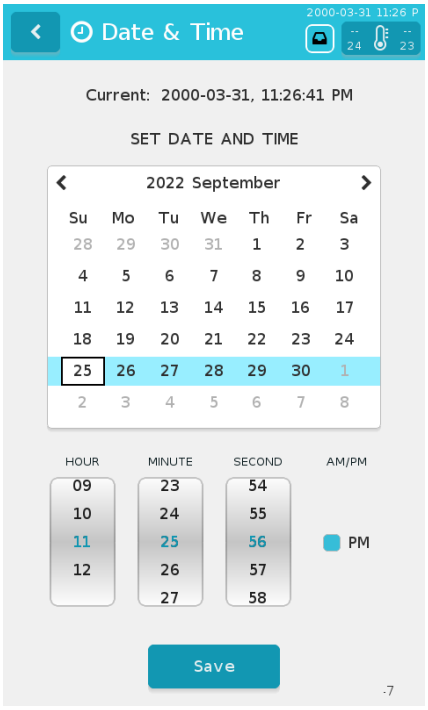
Step	Action
1	From the main menu, tap ***Recipes***.

Step	Action
2	Tap the delete button next to the recipe.  *Result:* A confirmation dialog appears on the screen.
3	Tap ***Yes*** to proceed with the deletion. Tap ***No*** to cancel the deletion and return to the ***Recipes*** menu. *Result:* The screen returns to the ***Recipes*** menu. The recipe slot where the recipe was previously stored is now empty.

5.3 Settings

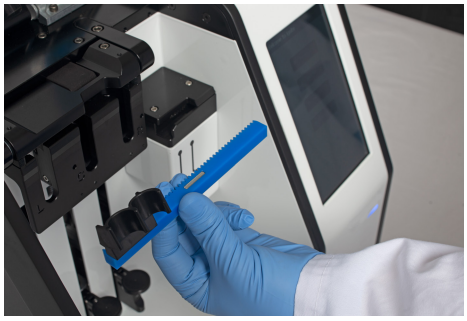
Change date and time

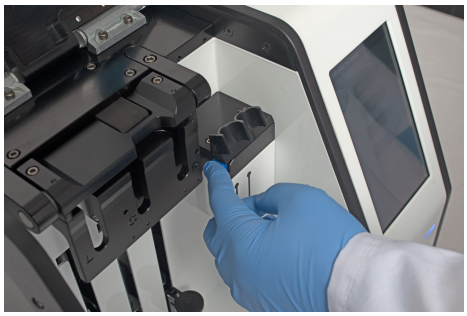
Follow the instructions below to change the date and time

Step	Action
1	From the main menu, tap ***Settings***.
2	Tap ***Date & Time***.
3	Select the date from the calendar. 
4	Use the three rollers to select the hour, minute, and second.
5	If applicable, check the ***PM*** box.
6	Tap ***Save*** to apply the settings. *Result:* The date and time are immediately updated in the ***Date & Time*** menu and in the information bar at the top of the screen.

5.4 Replace sample arm

Follow the instructions below to replace the installed sample arm with a different sized sample arm.

Step	Action
1	Open the lid of the instrument.
2	Pull the sample arm horizontally out of the holder. 
3	Hold the new sample arm with the tube holders on the left top side. 
4	Align the body of the sample arm with the holder on the instrument. 

Step	Action
5	Push the sample arm into the holder horizontally. 

6 Operation

About this chapter

This chapter gives instructions on how to operate Ignite and Ignite+ in a safe way.

In this chapter

6.1 Safety precautions

WARNING

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

WARNING

Hazardous substances and biological agents. When using hazardous chemical or biological agents, take all suitable protective measures, such as wearing protective clothing, glasses and gloves resistant to the substances used. Follow local and national regulations for safe operation and maintenance of this product.

CAUTION

Hot surface. Avoid direct contact with the heating block and the top surface of the rotating block during or after heating. Contact with hot surfaces during or directly after a procedure in which the heaters are on can cause burns.

6.2 Start-up and shutdown

Introduction

This section describes how to start and shut down the instrument.

Start the instrument

To start the instrument, press the power switch on the back of the instrument to the **I** position.

When the instrument starts, the following occurs:

- The user interface and status indicator are illuminated.
- When the system is ready to use, the user interface displays the main menu.

Shut down the instrument

To shut down the instrument, press the power switch on the back of the instrument to the **O** position.

6.3 Run a procedure

Introduction

This section provides instructions to run a procedure.

In this section

6.3.1 Workflow

The table below explains the main phases of a run.

Phase	Description
0	**Optional:** Pre-heat the system and reagents
1	Initiate the run using an existing recipe, or by starting a quick run ***Note:*** *When **Quick run** is chosen, all parameters must be entered manually.*
2	Load the cartridge
3	Load the syringes, collection tubes, and waste tubes ***Note:*** *The steps in this phase depend on whether the heaters are used.*
4	Start the formulation
5	After formulation is complete, remove the sample and waste tubes
6	Disconnect and dispose of used cartridge and syringes

6.3.2 Prerequisites and required materials

Prerequisites

The Ignite or Ignite+ must be installed by trained personnel. If syringe heating is used, the heating block must be installed by authorized Cytiva personnel.

The correct size of sample arm must be installed prior to running a procedure. See *Section 5.4 Replace sample arm, on page 73* for information about replacing the sample arm.

Required materials supplied by Cytiva

Prior to starting a procedure, make sure you have the following available:

Material	Description
Single use cartridge	Ignite instrument: One of the following cartridges: • Classic • NxGen • NxGen Dilution
	Ignite+ instrument: One of the following cartridges: • Classic • NxGen • NxGen Dilution • NxGen 500 • NxGen 500D
Heating inserts (optional)	If the procedure uses syringe heating: up to two heating inserts; one heating insert for each channel that uses heating. See *Section 3.5.1 Heating insert, on page 38* for information about heating insert compatibility.

Required materials supplied by the user

Prior to starting a procedure, make sure you have the following available:

Material	Description
Reagents	• Two reagents that are mixed in the microfluidic mixer of the cartridge. • If using dilution, a dilution solution. See *Section 9.2 Chemical resistance, on page 115* to determine if the reagents are compatible for use with the system.
Syringes	One syringe for each reagent (up to three syringes). See *Syringe compatibility, on page 112* for compatible syringes.
Sample collection tube	A collection tube that is large enough to hold the final sample volume, and that is chemically compatible with the reagents. See *Collection tube compatibility, on page 113* for compatible tubes.
Waste collection tube	A collection tube that is large enough to hold the start and end waste, and that is chemically compatible with the reagents. See *Collection tube compatibility, on page 113* for compatible tubes.

6.3.3 Optional: Preheat the system

Introduction

The Ignite and Ignite+ systems offer optional heating, for procedures that use pre-heated liquids. The heating block preheats the syringes and holds the temperature of the syringes in the C and R channels above ambient temperature for the duration of the run.

IMPORTANT
While C and R syringes are heated independently, they are only able to maintain a maximum offset of 30°C. For example, if the R syringe temperature is set to 75°C and the C syringe temperature is set to 25°C, the actual C syringe temperature will reach 45°C.

The table below gives the limitations on temperature for each of the instruments.

Instrument	Temperature
Ignite	Up to 75°C
Ignite+	Up to 65°C

Preheat the instrument

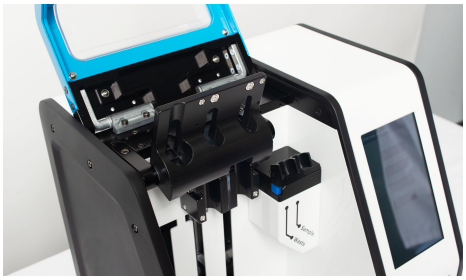
Before you begin, make sure that the heating insert or inserts are correctly sized for the syringes used in the run. See *Section 3.5.1 Heating insert, on page 38* for compatibility.

Note: *Only C and R channels can be used with heating.*

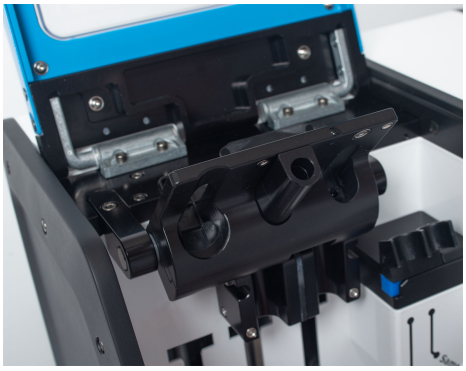
Step	Action
1	Open the lid of the instrument.
2	Rotate the rotating block upwards so that the underside of the cartridge is visible.

Step	Action

Result:



3 Insert the heating insert or inserts into the appropriate channel of the rotating block.

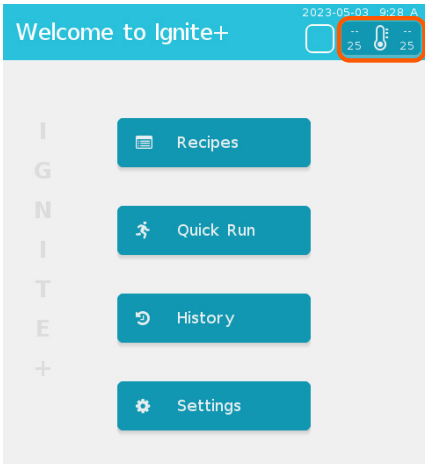


If using Ignite+ heating inserts, the three arrows on the insert must point in the direction of the fluid flow.

Result:
The heating inserts snap into place magnetically.

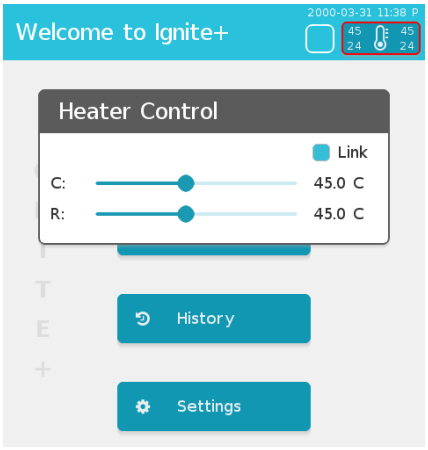
4 Rotate the rotating block down into the default position.

Step	Action
5	On the user interface, tap the heating control in the top right corner.



Result:
The ***Heater Control*** dialog appears on the screen.

6	Adjust the C and R sliders to the correct temperature.



Note:
To set the heaters to the same temperature, tap the check box next to ***Link****.*

Result:
The setpoint or setpoints chosen are shown in the top row of the heating control indicator. The heating block immediately begins to heat the syringe heaters. The actual temperature of each heater is displayed in the bottom row of the heating control indicator.

Step	Action

CAUTION

Hot surface. Avoid direct contact with the heating block and the top surface of the rotating block during or after heating. Contact with hot surfaces during or directly after a procedure in which the heaters are on can cause burns.

7 Tap anywhere on the screen outside the ***Heater Control*** dialog to exit the heater control.

8 Wait until the temperature of the heater or heaters displayed in the bottom row of the heating control indicator reaches the setpoint displayed in the top row.

Note:
Preheating generally takes less than ten minutes.

Proceed to the next section to start a run.

Tip: *Preheat the reagents in a wet or dry bath while you wait for the syringe heaters to reach the setpoint temperature. Make sure to heat the empty or filled syringes.*

6.3.4 Initiate a run

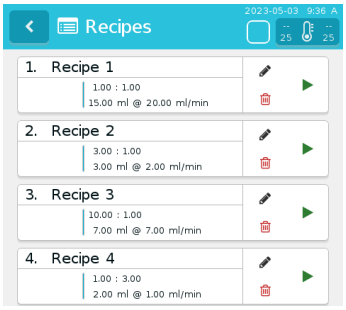
Introduction

There are two ways to initiate a run on the Ignite and Ignite+ systems:

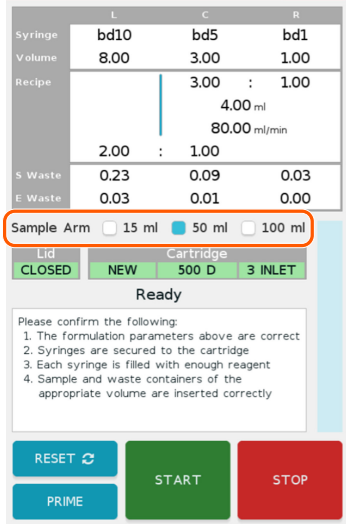
- Select a recipe: Select a set of saved parameters from the ***Recipes*** screen.
- Quick run: Enter all parameters manually on the ***Quick Run*** screen. This option is useful for unique formulations, or when a set of parameters are being refined.

Select a recipe

Follow the steps below to select a recipe.

Step	Action
1	Tap ***Recipes*** on the main menu. *Result:* The ***Recipes*** screen is shown. The recipe name and key parameters are shown for each recipe. 
2	Tap the run button to the right of the chosen recipe. *Result:* The formulation screen is shown. The recipe name is shown in the information bar at the top of the screen. The chosen parameters and next steps are also displayed on the screen.

Step	Action
3	If using Ignite+, select the sample arm size by tapping the ***Sample Arm*** check box.



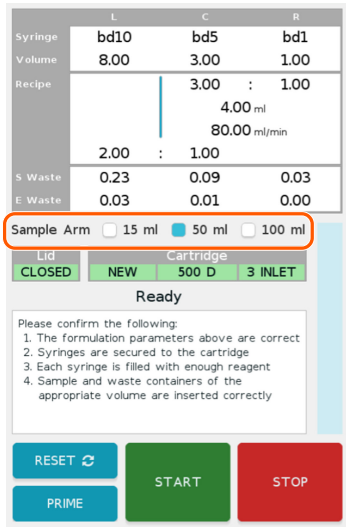
Proceed to the following sections to load the cartridge, syringes, and collection tubes. Refer to the formulation screen while preparing these items, as the syringes and required volumes are displayed in the formulation summary in the top half of the screen.

Quick run

Follow the steps below to perform a quick run.

Step	Action
1	Tap ***Quick Run*** on the main menu. *Result:* The ***Quick Run*** screen is shown.
2	Enter the syringe selection, mixing parameters, and waste parameters. See *Section 5.1 Parameters, on page 56* for parameter ranges and considerations. *Result:* After all parameters are entered, the system validates the parameter values. If any validation errors are present, the errors are listed in red at the bottom of the screen. See *Section 5.1.4 Parameter validation, on page 67* for more information.
3	Tap ***Next*** at the bottom right of the screen.

Step	Action
	Result: The formulation screen appears. The chosen parameters and next steps are displayed on the screen.
4	If using Ignite+, select the sample arm size by tapping the ***Sample Arm*** check box.



Proceed to the following sections to load the cartridge, syringes, and collection tubes. Refer to the formulation screen while preparing these items, as the syringes and required volumes are displayed in the formulation summary in the top half of the screen.

6.3.5 Prepare the cartridge

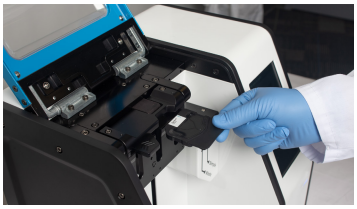
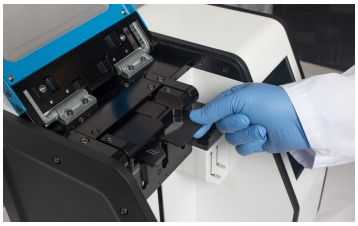
Load a cartridge

Follow the steps below to load a two- or three-inlet cartridge.

Step	Action
1	Open the lid of the instrument.
2	If using a two-inlet cartridge, insert the cartridge adapter with the arrows facing upwards into the rotating block above the L pusher.


Result:
The cartridge adapter snaps into place magnetically.

3	Insert the cartridge into the rotating block with the cartridge label facing up.

Result:
The cartridge snaps into place magnetically.

4	Make sure the cartridge indicator in the information bar of the user interface is green. See *Cartridge indicator states, on page 30* for information about the status of the cartridge.

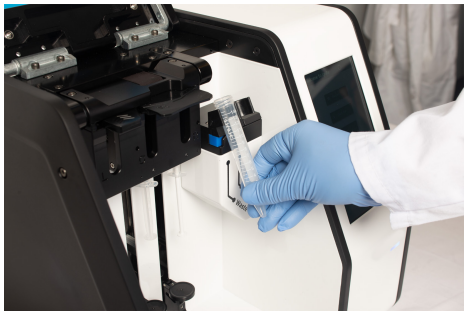
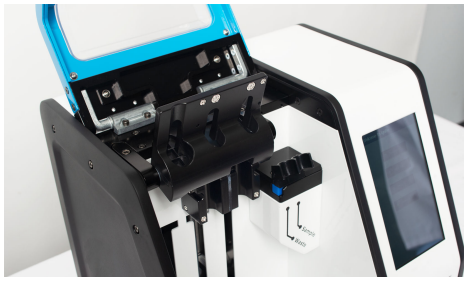
Optional: Prime the cartridge

The option for a short priming sequence is available. However, priming is not required when using the system due to the following design features:

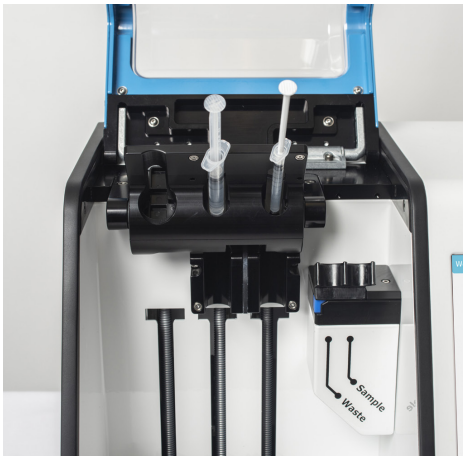
- Single-use cartridges remove the risk of cross-contamination from prior runs.
- Cartridges are manufactured using a highly automated process in a cleanroom environment, minimizing the potential for leaks, blockages, and debris.

- Precision calibrated syringe detection is designed for optimal fluid injection into an empty fluid path.
- Start waste volumes are sufficient to wet and flush the channels prior to formulation.

Follow the steps below to prime the system. If not using priming, proceed to *Section 6.3.6 Load syringes and collection tubes, on page 94*.

Step	Action
1	Insert the waste collection tube into the left clip of the sample arm. 
2	Fill syringes with the priming solvents. At least 6 mm (¼ inch) of fluid must be added to each syringe.
3	Open the lid of the instrument.
4	Rotate the rotating block upwards so that the underside of the cartridge is visible.  *Result:* 

Step	Action
5	Insert the R, C, and optional L syringes into the respective channels of the rotating block.



6	Secure the syringes to the cartridge by doing one of the following:

a. Syringes with Luer fittings: Twist the syringe to engage the Luer connection.

NOTICE
Do not tighten the Luer connection too much. Tightening the connection too much can damage the syringe and the cartridge.

b. Syringes without Luer fittings: Push the syringe until you meet resistance.

NOTICE
Do not insert the syringe too far. Inserting the syringe too far can damage the syringe and the cartridge.

7	Close the lid of the instrument.
8	Tap ***PRIME*** at the bottom left of the user interface.

Result:
The syringe pushers travel approximately 6 mm after detecting a syringe, which is equivalent to:

- approximately 0.1 mL when using a 1 mL syringe, or

Step	Action
	• approximately 1 mL when using a 10 mL syringe.
9	Open the lid and remove the syringes.

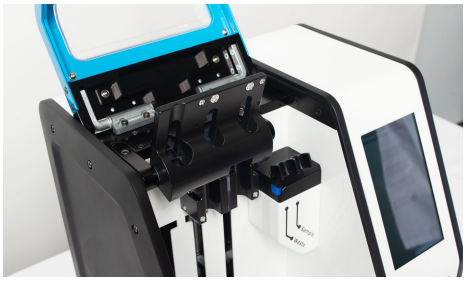
Proceed to the following sections to load the syringes with the reagents for the run.

6.3.6 Load syringes and collection tubes

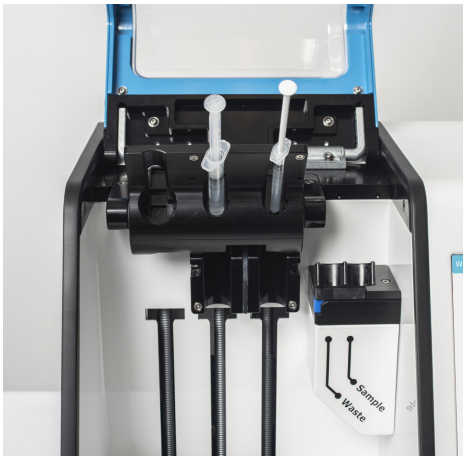
Load syringes and collection tubes without preheating

Before you begin, make sure the correct sample arm is installed in the instrument, based on the size of the collection tubes. To change the sample arm, see *Section 5.4 Replace sample arm, on page 73*.

Follow the steps below to load the reagents and syringes, and load the collection tubes.

Step	Action
1	Load the reagents into the syringes following your internally validated procedure. Make sure there are no air bubbles at the tip of the syringes.
2	Remove any air bubbles at the tip of the syringes, making sure the fluid meniscus at the tip of the syringe is as flat as possible to prevent pre-mixing of the fluids when loading the syringes. ***Tip:*** *To prevent excess fluid from collecting in the Luer fitting, hold a lint-free laboratory tissue near the tip of the syringe when expelling air bubbles.*
3	Rotate the rotating block upwards so that the underside of the cartridge is visible.  *Result:* 

Step	Action
4	Insert the R, C, and optional L syringes into the respective channels of the rotating block.



5	Secure the syringes to the cartridge by doing one of the following:

a. Syringes with Luer fittings: Twist the syringe to engage the Luer connection.

NOTICE
Do not tighten the Luer connection too much. Tightening the connection too much can damage the syringe and the cartridge.

b. Syringes without Luer fittings: Push the syringe until you meet resistance.

NOTICE
Do not insert the syringe too far. Inserting the syringe too far can damage the syringe and the cartridge.

Step	Action
6	Rotate the rotating block down into the default position. 
7	Install the sample collection tube in the right clip of the sample arm and the waste collection tube in the left clip of the sample arm. ***Note:*** *Proper placement of the sample and collection tubes is critical to the avoid unnecessary spillage.* • If using the Ignite sample arms, or the 15 mL or 50 mL sample arms on Ignite+: Make sure that the tubes sit as low as possible in the clips. The threads of the tubes should sit directly above the plastic clips.  • If using the 100 mL sample arm on Ignite+: Make sure the lip of the waste tube is pressed upwards to sit as high as possible against the middle ridge of the tube holder. Make sure the lip of the 100 mL sample tube is pressed downwards to sit as low as possible on the top edge of the tube holder.

Step	Action
	
8	Close the lid of the instrument.

Proceed to *Section 6.3.7 Start the formulation, on page 101* to start the formulation.

Load syringes and collection tubes with preheating

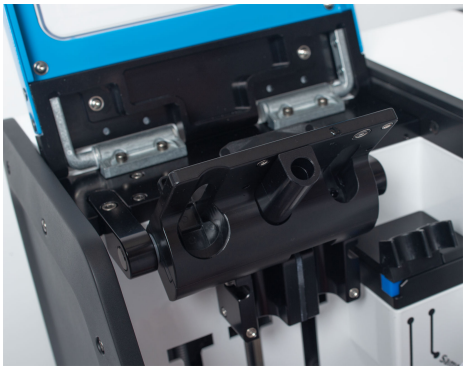
> **CAUTION**
>
> **Hot surface.** Avoid direct contact with the heating block and the top surface of the rotating block during or after heating. Contact with hot surfaces during or directly after a procedure in which the heaters are on can cause burns.

If syringe heating is used in the run, the syringes and reagents must be preheated before the preheated reagents can be loaded.

Before you begin, make sure:

- The reagents are preheated.
- The correct heating inserts are installed, based on the size of the syringes.
- The correct sample arm is installed in the instrument, based on the size of the collection tubes. To change the sample arm, see *Section 5.4 Replace sample arm, on page 73*.

Follow the steps below to preheat the syringes, load the reagents and syringes, and load the collection tubes.

Step	Action
1	Rotate the rotating block upwards so that the underside of the cartridge is visible.  *Result:* 
2	Insert the empty syringes selected for the run into the heating inserts in the R and C channels of the rotating block. ***Tip:*** *While waiting for the syringes to be preheated, change the sample arm if necessary, and load the collection tubes.*
3	Remove the syringes from the rotating block.
4	Load the preheated reagents into the syringes.
5	Remove any air bubbles at the tip of the syringes, making sure the fluid meniscus at the tip of the syringe is as flat as possible to prevent pre-mixing of the fluids when loading the syringes. ***Tip:*** *To prevent excess fluid from collecting in the Luer fitting, hold a lint-free laboratory tissue near the tip of the syringe when expelling air bubbles.*
6	Insert the R and C syringes into the heating inserts in the right and center channels, respectively.

Step	Action
7	**Optional.** Insert the L syringe into the left channel of the rotating block.
8	Secure the syringes to the cartridge by doing one of the following: a. Syringes with Luer fittings: Twist the syringe to engage the Luer connection. **NOTICE** Do not tighten the Luer connection too much. Tightening the connection too much can damage the syringe and the cartridge. b. Syringes without Luer fittings: Push the syringe until you meet resistance. **NOTICE** Do not insert the syringe too far. Inserting the syringe too far can damage the syringe and the cartridge.
9	Install the sample collection tube in the right clip of the sample arm and the waste collection tube in the left clip of the sample arm. ***Note:*** *Proper placement of the sample and collection tubes is critical to the avoid unnecessary spillage.* • If using the Ignite sample arms, or the 15 mL or 50 mL sample arms on Ignite+: Make sure that the tubes sit as low as possible in the clips. The threads of the tubes should sit directly above the plastic clips.  • If using the 100 mL sample arm on Ignite+: Make sure the lip of the waste tube is pressed upwards to sit as high as possible against the middle ridge of the tube holder. Make sure the lip of the 100 mL sample tube is pressed downwards to sit as low as possible on the top edge of the tube holder.

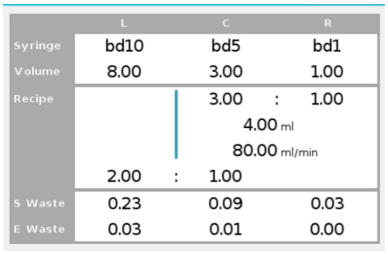
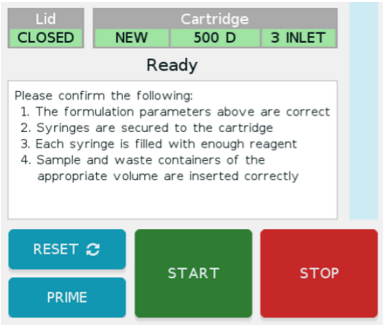
Step	Action
	
10	Close the lid of the instrument.

Proceed to the next section to start the formulation. It is recommended to start the formulation as soon as possible after loading the syringes.

CAUTION
Do not wait longer than 3 minutes between inserting the syringes and starting the formulation. Leaving the heating block on with the syringes inserted can cause ignitable vapor to form inside the instrument.

6.3.7 Start the formulation

Follow the steps below to start and monitor the formulation.

Step	Action
1	Review the parameters displayed on the formulation screen. 
2	Make sure that the final actions listed on the screen are complete.  ***Note:*** *If the correct cartridge is installed, and the lid is closed, the **START** button is green.*
3	If there are any errors listed in red on the screen, the errors must be corrected before proceeding with the formulation. See *Error messages and suggested corrective actions, on page 110* for troubleshooting.
4	Tap ***START***. *Result:* The formulation begins.

6.3.8 Monitor the formulation

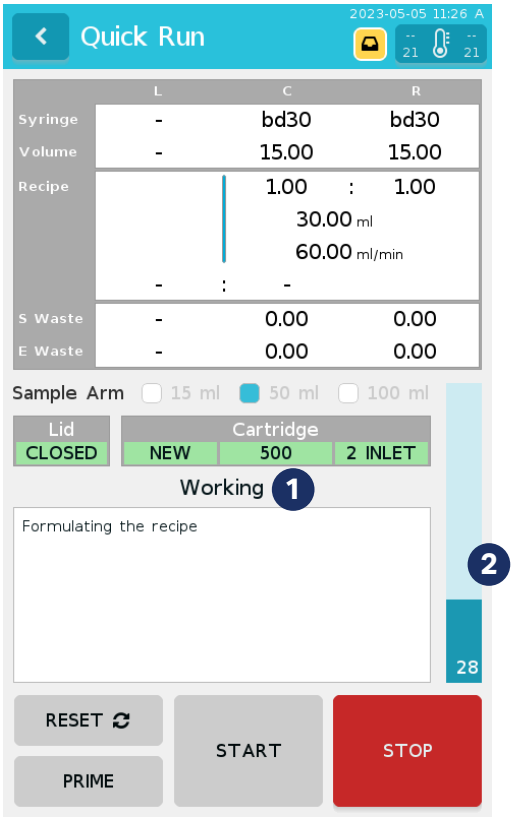
Overview

Monitor the status of the procedure on the screen.

The status text (1) displays one of the following:

- ***Working***: The formulation is ongoing.
- ***Interrupted***: The lid has been lifted or ***STOP*** has been pressed.
- ***Completed***: The formulation is complete.

The progress is displayed in the blue progress bar (2) to the right of the screen.



Interrupt the formulation

During the formulation, the user can interrupt the formulation at any time. If the lid of the instrument its opened at any time during the formulation, the formulation is also interrupted. Follow the steps below to interrupt the formulation.

Step	Action
1	Tap ***STOP***, or open the lid. *Result:* The instrument stops all actions immediately.
2	Tap ***RESET*** to return all system components to their home positions.
3	Collect any sample already in the sample tube and start a new procedure.

6.3.9 End a run

Follow the steps below to end a run.

Make sure that the syringe pushers have returned to their home positions and the status on the user interface displays ***Completed***.

Step	Action
1	Open the lid of the instrument.
2	Remove the sample and waste collection tubes.
3	Rotate the rotating block upwards.
4	Remove the syringes.
5	Rotate the rotating block into the default position and remove the cartridge.
6	If applicable, remove the cartridge adapter.
7	If applicable, wait for the heating block to cool and remove the heating inserts.
8	Dispose of the used cartridge and syringes according to local regulations.
9	Clean any spills or drips immediately. See *Section 7.4 Routine cleaning, on page 109* for cleaning instructions. ***Note:*** *When running a procedure on the Ignite+ instrument, some spillage is expected during the procedure due to the high flow rates. The spillage is minimized as much as possible by the system.*

7 Maintenance

About this chapter

This chapter provides information about maintenance that should be performed by users of Ignite and Ignite+.

To ensure that the system works according to specifications, planned maintenance should be performed annually by a Cytiva service engineer, or service personnel authorized by Cytiva.

In this chapter

7.1 Safety precautions

WARNING

Disconnect power. Always disconnect power from the instrument before performing any maintenance task.

WARNING

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

7.2 Service and preventive maintenance

Introduction

Regular service and maintenance of Ignite is necessary to maintain optimal condition and to extend the operational lifetime of the system components.

Service and preventive maintenance work must be performed according to Cytiva recommendations, and according to the maintenance instructions of the component manufacturers.

Service frequency

The requirements for frequency of service and preventive maintenance depend on the frequency of use and the specific applications performed.

A general recommendation is to schedule one service and preventive maintenance visit every year. Adhere to the maintenance intervals.

If any component fails, it is recommended that it be replaced immediately to avoid further damage to the system. Adhering to these guidelines will maximize the lifespan of the system.

Service agreements

Contact your Cytiva representative for information about frequency of service requirements to suit individual process needs and for details of the Cytiva service agreement options available for each instrument.

7.3 Cleaning before planned service

Introduction

This section describes what the user must do before a planned service can be performed.

Cleaning before planned maintenance/service

To protect the 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.

7.4 Routine cleaning

Immediate clean up is recommended for any liquid spilled or dripped inside the instrument. Cleaning can also be performed as a preventative measure.

The most common area for spills, drips, and material build up is the paddles attached to the pushers. The paddles are critical for syringe detection and in minimizing waste volumes.

To clean the paddles, wipe the surface of the paddles, the paddle hinge, and the paddle underside with ethanol or isopropyl alcohol.

If fluid is spilled on the sample arm, it may become sticky, preventing it from moving properly during formulation. To clean the sample arm, remove it from the instrument as described in *Section 5.4 Replace sample arm, on page 73*.

To clean the instrument body, lid, and all internal components, wipe down the surfaces with one of the following:

- Warm water and a mild non-abrasive detergent
- Ethanol
- Isopropyl alcohol

The lid should be wiped with a soft cloth to avoid scratches that could impact visibility.

8 Troubleshooting

About this chapter

This chapter provides information to assist users and service personnel to identify and correct problems that may occur when operating the product.

If the suggested actions in this guide do not solve the problem, or if the problem is not covered by this guide, contact your Cytiva representative for advice.

Error messages and suggested corrective actions

Message text	Suggested corrective action
Cannot formulate	Do one of the following to continue with operation: • Select the appropriate sample arm • Insert the missing cartridge • Close the lid of the instrument
Some fields are missing	Do one of the following to continue with operation: • Enter a value for the parameter ***Dilution ratio*** • Deselect the syringe in the L channel
Instrument is in safe mode	Close the lid and tap ***Reset*** to return all system components to their home positions
[L, C, R] syringe is missing or Paddle may need cleaning	Do one of the following to continue with operation: • Attach the missing syringe or syringes • If the syringes are attached, the paddle might be sticky. Clean the paddles as described in *Section 7.4 Routine cleaning, on page 109*.
Heater Not Attached	Contact your Cytiva representative to have the heating option installed on the system. See *Contact information for support, on page 119*.

9 Reference information

About this chapter

This chapter lists the technical specifications of Ignite and Ignite+. The chapter also includes a chemical resistance guide, recycling information, regulatory information, and ordering information.

In this chapter

9.1 Specifications

Introduction

This section describes the specifications for the product.

Technical specification

Parameter	Specification
Supply voltage	100 to 240 V AC
Frequency	50/60 Hz
(W × D × H)	38 × 34 × 38 cm (15 × 13.4 × 15 in)
Weight	16 kg (35.3 lb)

Syringe compatibility

The Ignite and Ignite+ systems are designed to be used with specific syringes. The table below gives the product name and compatible sizes for syringes.

Product	Compatible sizes
BD Luer-Lok syringes (centered tip)	3, 5, 10, 20, 30 mL
BD Slip Tip syringes (centered tip)	1, 3, 5, 10, 20, 30 mL
B. Braun Injekt Luer Solo or Luer-Lock Solo syringes (centered tip)	1, 2*, 5, 10, 20 mL
B. Braun Omnifix Luer Solo or Luer-Lock Solo syringes (centered tip)	1, 3, 5, 10, 20, 30 mL
Terumo Luer Lock or Luer Slip hypodermic syringes (centered tip)	1, 2.5*, 3, 5, 10, 20, 30 mL
Shinva Ande syringes	1, 2, 5, 10 mL
KDL syringes	1, 2, 5, 10 mL
WEGO syringes	2, 5, 10 mL
KOVAX syringes	1 mL

* Not compatible with heating accessories. Must be used with syringe extenders for optimal performance in all other cases

Consult the manufacturer of the syringes for chemical compatibility.

NOTICE
Do not use polycarbonate syringes for the solvent phase. Use a syringe made from polypropylene instead.

Note: *Some syringes, particularly those that have an elastomeric plunger seal, are made of more than one fluid contacting material.*

Collection tube compatibility

Certain collection tubes have been validated for use with the instruments, and the system performance has been optimized for these products. The table below gives the compatible tubes for sample collection and waste collection.

Tube type	Compatible tubes
Waste collection	15 mL centrifuge tubes
Ignite sample collection	15 mL centrifuge tubes 50 mL centrifuge tubes
Ignite+ sample collection	15 mL centrifuge tubes 50 mL centrifuge tubes 100 mL Nalgene round-bottom centrifuge tubes

Note: *15 mL and 50 mL Falcon conical tubes have been validated for geometric characteristics.*

If you choose to use an alternate collection tube, consult the manufacturer of the sample collection tubes for chemical compatibility and the required level of cleanliness of the external environment. Consider the mixture of solvents present in the final formulation.

Environmental requirements

The table below describes the environmental requirements for Ignite and Ignite+ system.

Parameter	Requirement
Allowed location	Indoor use only
Ambient temperature	15°C to 35°C
Relative humidity	25% to 65%, non-condensing
Pressure	70 to 106 kPa
Altitude	Up to 2000 m

Parameter	Requirement
Pollution degree of the intended environment	Pollution degree 2

9.2 Chemical resistance

Cartridges

The Ignite and Ignite+ cartridges are composed of non-toxic cyclo olefin polymer (COP), which offers good resistance to a wide range of temperatures and chemicals, including acids and bases.

A list of chemicals to which COP exhibits good chemical resistance is provided below:

NOTICE
Chemicals not on this list can be validated by the user under conditions representative of the intended use. However, take caution with oils and solvents of low polarity.

Chemical	Usage
Acetone	Solvent
Acetic acid 99%	Aqueous solution
Ammonia 28%	Aqueous solution
Dimethyl sulphoxide (DMSO)	Solvent
DMF (N,N-dimethylformamide)	Solvent
Ethyl alcohol	Solvent
Fluorinated oil	Solvent
Formadide 50%	Aqueous solution
Glycerine	Aqueous solution
Hydrochloric acid 35%	Aqueous solution
Isopropyl alcohol	Solvent
Methyl alcohol	Solvent
Methyl cellosolve	Solvent
Methyl phenyl silicon oil	Solvent
Polyethylene glycol 50% (PEG4000S)	Aqueous solution
Saline	Aqueous solution
Sodium hydroxide, NaOH	Aqueous solution
Sulfuric acid 95%	Aqueous solution
Tween 20 10%	Aqueous solution

Chemical	Usage
Tween 80 10%	Aqueous solution
Urea 50%	Aqueous solution

9.3 Recycling information

Introduction

This section contains information about the decommissioning of the product.

CAUTION

Always use appropriate personal protective equipment when decommissioning the equipment.

Decontamination

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

Disposal of the product

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

Recycling of hazardous substances

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

Disposal of electrical components

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

9.4 Regulatory information

Introduction

This section lists the regulations and standards that apply to the product. Your product 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

9.4.1 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 manufacturer	Global Life Sciences Solutions Canada ULC 4560 Tillicum St Burnaby, BC, V5J 5L4 Canada
Telephone number of manufacturer	+1 604 453 8660

9.4.2 European Union and European Economic Area

Introduction

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

Conformity with EU Directives

Refer to 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.

9.4.3 Great Britain

Introduction

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

Conformity with UK Regulations

Refer to 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 are 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.

9.4.4 North America

Introduction

This section describes the information that applies to the product in the United States of America 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.

Canada RSS: General statement

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions:

1. This device may not cause interference.
2. This device must accept any interference, including interference that may cause undesired operation of the device.

L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes:

1. L'appareil ne doit pas produire de brouillage;
2. L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

9.4.5 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 Component 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)
NanoAssemblr Ignite NIN0001	X	0	0	0	0	0
NanoAssemblr Ignite+ 1001413	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.

9.4.6 South Korea

Introduction

This section describes the information that applies to the product in the Republic of Korea.

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 방송통신 기자재)

이 기기는 업무용환경에서 사용할 목적으로 적합성평가를 받은 기기

로서 가정용 환경에서 사용하는 경우 전파간섭의 우려가 있습니다.

9.4.7 General regulatory statements

Introduction

This section describes the information that is applicable to more than one geographical region.

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

NOTICE

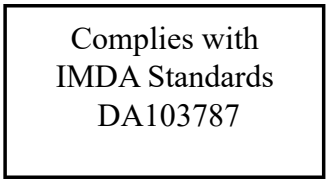
This equipment is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments.

9.4.8 Other regulations and standards

Introduction

The following marking appears on the product to indicate compliance with radio-emission regulations in the respective regions.

Singapore



The dealer licence number for Ignite and Ignite+ is DA103787.

South Africa

Thailand

เครื่องโทรคมนาคมและอุปกรณ์นี้ มีความสอดคลอ้ งตามขอ้ กำหนดของ กสทช.

This telecommunication equipment is in compliance with NBTC requirements.

This radio communication equipment is exempted to possess a license, user license, or radio communication station license as per NBTC notification regarding radio communication equipment and radio communication station has been exempted for license according to radio communication act B.E.2498.

Taiwan

取得審驗證明之低功率射頻器材，非經核准，公司、商號或使用者均不得擅自變更頻率、加大功率或變更原設計之特性及功能。

低功率射頻器材之使用不得影響飛航安全及干擾合法通信；經發現有干擾現象時，應立即停用，並改善至無干擾時方得繼續使用。前述合法通信，指依電信管理 法規定作業之無線電通信。低功率射頻器材須忍受合法通信或工業、科學及醫療用電波輻射性電機設備之干擾。

Without permission granted by the NCC, any company, enterprise, or user is not allowed to change frequency, enhance transmitting power or alter original characteristic as well as performance to approved low power radio-frequency devices.

The low power radio-frequency devices shall not influence aircraft security and interfere legal communications; If found, the user shall cease operating immediately until no interference is achieved. The said legal communications means radio communications is operated in compliance with the Telecommunications Management Act. The low power radio-frequency devices must be susceptible with the interference from legal communications or ISM radio wave radiated devices.

9.5 Ordering information

Find ordering information online

The latest information about product offerings and product codes is available online. Follow the steps below to find lipid nanoparticle formulation systems, reagents, cartridges, or other accessories.

Step	Action
1	Navigate to *cytiva.com*.
2	Search for the product name or product category.
3	Navigate to the relevant product page.
4	Scroll to ***Product Specifications*** to find the product names, codes, and other ordering information.

9.6 Health and Safety Declaration Form

On site service

cytiva

On Site Service Health & Safety Declaration Form

Service Ticket #:	

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

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

Equipment type / Product No:		Serial No:	

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

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

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:			

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

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cytiva.com

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

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