NanoAssemblr™ Commercial Formulation System

Operating Instructions

Original instructions

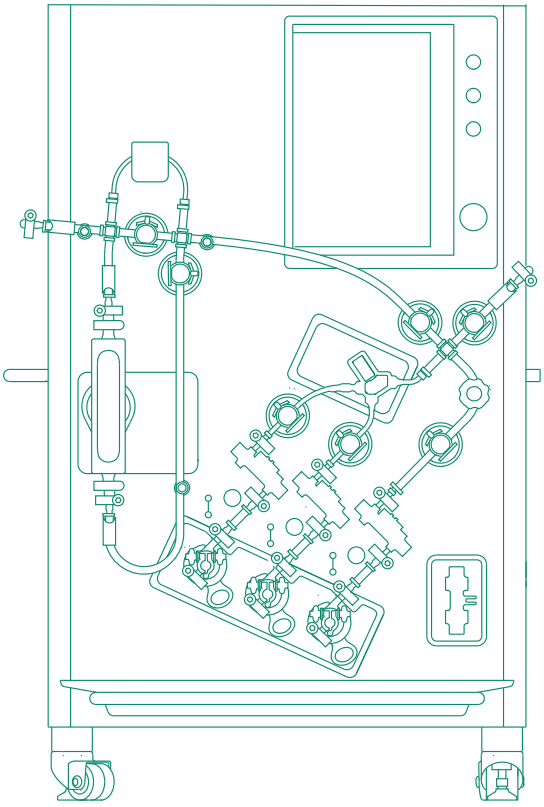


Table of Contents

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™ Commercial Formulation System is intended for the controlled manufacture of nanomedicines. The product is intended to be used by trained laboratory staff members.

The system is not intended for diagnostic purposes.

The system is allowed for use in potentially explosive atmosphere (hazardous locations) only as classified on the system nameplate.

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 NanoAssemblr Commercial Formulation System, and covers the Commercial Formulation System instrument, embedded software, and accessories.

Throughout this manual, NanoAssemblr Commercial Formulation System is also referred to as Commercial Formulation System and "the system."

Notes and tips

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

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

Typographical conventions

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

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

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

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

1.3 Associated documentation

Introduction

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

User documentation for Commercial Formulation System

The user documentation is listed in the table below.

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

Documentation	Main contents
NanoAssemblr Commercial Formulation System Operating Instructions (1002349) (this document)	Instructions needed to prepare and operate the Commercial Formulation System 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.
NanoAssemblr Commercial Formulation System User Manual (D101414)	Additional detailed information on the system, software features, and operation of the software. Tips on how to get the most out of the system when running it. This document is referred to as *the system User Manual* in this document.
NanoAssemblr Commercial Formulation System Unpacking Instructions (D101394)	Instructions for handling the delivery package and unpacking the system. This document is referred to as *the system Unpacking Instructions* in this document.
NanoAssemblr Commercial Formulation System Site Preparation Guide (D101415)	Information needed to prepare the site for installation and use of the system. This document is referred to as *the system Site Preparation Guide* in this document.

Access user documentation online

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

1.4 Abbreviations

Introduction

This section explains abbreviations that appear in the user documentation for Commercial Formulation System.

Abbreviations

Abbreviation	Definition (English)	Translation (local language)
CIP	Cleaning-in-place	Cleaning-in-place
HMI	Human machine interface	Human machine interface
MCV	Manual control valve	Manual control valve
OPC	Open platform communications	Open platform communications
PLC	Programmable logic controller	Programmable logic controller
RFID	Radio Frequency Identification	Radio Frequency Identification
TC	Hygienic tubing connection	Hygienic tubing connection
UA	Unified architecture	Unified architecture
UPS	Uninterruptible power supply	Uninterruptible power supply

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. It also contains important notices for critical software or application information. 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.

IMPORTANT

IMPORTANT indicates instructions that are essential for the software or application to function.

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

Risk assessment. Perform a risk assessment for the process or process environment. Evaluate the effects the use of the product and the operational processes may have on the classification of the hazardous area. The process can cause the hazardous area to increase or the zone classification to change. Implement the risk reduction measures needed, including use of personal protective equipment.

WARNING

All installation, maintenance, operation, and inspection must be carried out according to local regulations by adequately trained personnel.

WARNING

Accessories. Use only accessories supplied or recommended by Cytiva.

WARNING

Emergency stop. Pressing the **EMERGENCY STOP** does not automatically depressurize the flow path.

WARNING

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

CAUTION

Fall hazard. Do not step on the bumper on the front of the instrument. The bumper can break and cause injury to the user.

Personal protection

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.

WARNING

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

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

Flammable liquids and explosive environment

WARNING

Explosion hazard. The classification of the product is valid only when it is used according to the explosion hazard related safety instructions in this and the subsequent chapters. The information is suggested best working practice, but does not take precedence over individual responsibilities or local regulations.

WARNING

Explosion hazard: Risk assessment. When using the system 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 leakage in case of failure or breakage of the system. Prepare procedures for handling leakages and testing after corrective actions.
- Risk of smaller leakages during maintenance. Make sure there are no active ignition sources in the area during maintenance.
- Risk of fire. Wipe down the instrument with a damp cloth, when in dry ambient conditions. In dry ambient conditions static build up can occur and static discharge from the operator is a potential source of ignition.
- Risk of fire. Remove the collection vessels immediately after the formulation is completed and handle the liquids according to your SOPs. Depending on the input reagents, the collected waste and formulation liquids might be flammable.
- Risk of fire. If there is no path to ground in either the input or the output vessels, there is potential for charge build up in the output formulation. Follow local regulations for handling liquids in a non-conductive container in environments where there is an explosion hazard.

WARNING

Explosion hazard. Before maintenance, or if the system is to be moved to a non-hazardous area (area not classified as potentially explosive atmosphere or hazardous location), make sure that any flammable solvents have been flushed out from the system.

WARNING

Explosion hazard. When working in potentially explosive atmospheres, always use the following to avoid static build up:

- Suitable clothing.
- Non-sparking tools rated for the explosive atmosphere.
- Anti-static cleaning cloths.

WARNING

Explosion hazard. Before starting to use the system, make sure that there are no leakages in the system or in connections to it.

WARNING

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

WARNING

Explosion hazard. Remove any external ignition sources or open flames in the vicinity of the unit when operating the unit with flammable liquids.

WARNING

Explosion hazard: Never open panels and access doors on the instrument when the instrument is energized in a potentially explosive atmosphere.

WARNING

Explosion hazard. Fluid vessels holding flammable liquids must be secured and sealed to prevent exposure of the fluid to the environment.

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 (V AC)
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 system:

Label	Description
	**Warning!** Read the user documentation before using the system. Do not open any covers or replace parts unless specifically stated in the user documentation.
	**Warning! Crush risk.** Never put your fingers or any objects other than the intended tubing in the pinch valve openings. Make sure that clothing or other equipment does not get caught in the pinch valves.
	**Warning! Rotating rollers/cogwheels.** Never touch the pump or pump lid while the pump is running.

2.3 Emergency procedures

Introduction

WARNING

Pressurized flow path. During a power failure or emergency stop, the equipment can remain pressurized. Make sure all lines and vessels are depressurized before opening a line or vessel.

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

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

Emergency shutdown

In an emergency situation, follow the steps below to shut down the system.

Step	Action
1	Push the **EMERGENCY STOP** button on the front of the instrument.

Result:

All pump motors stop immediately. All pinch valves are closed. An alarm is triggered.

If the system is running a ***Formulate*** unit procedure when the **EMERGENCY STOP** button is pressed, the system is set in ***Pause*** mode.

Note:
At this point it is possible to close and save the batch if it is safe to do so. Refer to the system User Manual, see *User documentation for Commercial Formulation System, on page 8*.

Step	Action
2	Turn the power switch to the OFF position (**O**) to completely turn off power to the system. 
3	Disconnect the isolation switch, or unplug the instrument.
4	Shut off the valve on the air supply line.

Power failure

The following table describes the consequences of a power failure.

Power failure to...	will result in...
Commercial Formulation System	• The run is interrupted immediately and the instrument stops formulating. ***Note:*** *The fluid already dispensed can be collected and saved.* • The flow kit that is installed at the time of the power failure might be considered used, depending on when the power failure occurred. If using NxGen™ commercial manufacturing flow kit, the used flow kit must be replaced with a new flow kit upon restart.

Power failure to...	will result in...
Compressed air system	A low pressure alarm is generated. • If the system is idle at the time of power failure, the user will be prevented from starting any new steps. • If the system is in the middle of an install, uninstall, prime or calibration, the step will be stopped. • If the system is in the middle of a formulation, the system will pause the formulation. • The formulation can be resumed after the air pressure is restored and all alarms are cleared.

Restart after power failure or emergency shutdown

Follow the instructions below to restart the system after a power failure or emergency shutdown.

Step	Action
1	Make sure that the power switch is in the OFF position (**O**).
2	Make sure that the condition that caused the power failure or emergency shutdown is corrected.
3	Make sure that the valve on the air supply line is open.
4	Turn on power to the system by turning the power switch to the ON position (**I**).

Result:
The user interface starts up and the purge cycle begins, which can last up to 60 seconds. When purging is complete, all electrical components that rely on the internal purge and pressurize cabinet for explosion protection turn on, and the system is fully functional.

Step	Action
	Note: *If a batch was open when the system shut down, the batch is automatically saved and closed upon restarting the system.*

3 System description

About this chapter

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

In this chapter

3.1 Explosive atmosphere

Classification

The system is classified by a third party according to ATEX/IECEx and Hazardous Locations requirements. For the classification, see *Explosive atmosphere and hazardous location classifications, on page 186* or the system nameplate.

The classification of the system is only valid when it is installed, set up and used according to the explosive atmosphere safety instructions in the *Chapter 2 Safety instructions, on page 11* chapter and subsequent chapters.

Component rating

All components in the system flow path, such as pumps, valves, and sensors are classified according to the prevailing explosive atmosphere standards.

3.2 System overview

Overview of Commercial Formulation System

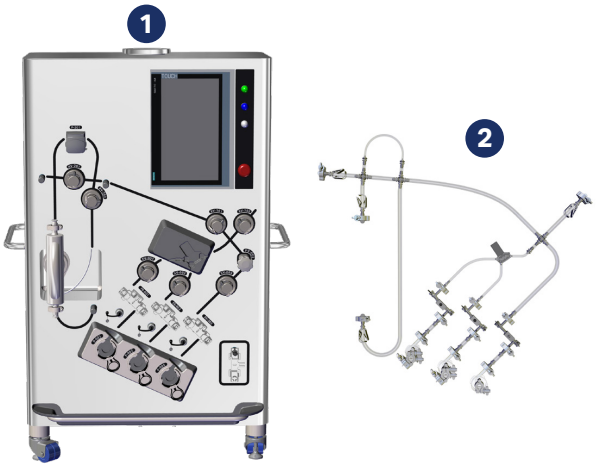
Commercial Formulation System includes the instrument, flow kit, and accessories. The instrument is operated and controlled from the touchscreen.

The main features of the system are as follows:

- The instrument is free standing, with adjustable leveling feet to lift the instrument off the casters.
- The fluid-handling flow kits are installed on the front of the instrument to formulate the lipid nanoparticles (LNPs).
- The instrument can be connected to the Ethernet box that is provided with the system, which enables the user to transfer data to an external server.

Illustration of the system

The illustration below shows the system.



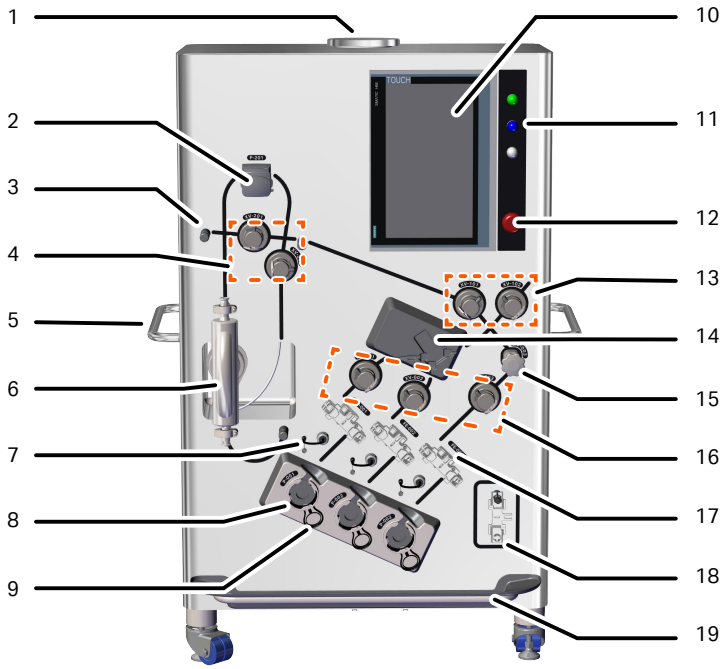
Part	Description
1	Commercial Formulation System
2	NxGen commercial flow kit (ordered separately)

3.3 Illustrations of the instrument

Introduction

This section provides illustrations that show the main components of the instrument. For further details on all components and sensors, see *Section 3.4 Instrument components, on page 29*.

Instrument front view



The main components of the instrument visible in the illustration are listed below.

Part	Description
1	Air vent
2	Peristaltic pump **P-201**
3	Tube supports
4	Waste (**XV-201**) and calibration (**XV-202**) pinch valves
5	Handle for moving the instrument
6	Calibration flow meter

Part	Description
7	Flow meter cables connected to dummy connectors
8	Centrifugal pumps **P-001**, **P-002**, **P-003**
9	Pump head clips
10	User interface
11	Status indicator lights
12	Emergency stop button
13	Output pinch valves **XV-101**, **XV-102**
14	RFID module with NxGen cartridge holder
15	Manual control valve **PV-003**
16	Input pinch valves **XV-001**, **XV-002**, **XV-003**
17	Flow meter housing **FE-001**, **FE-002**, **FE-003**
18	Storage for flow meter covers
19	Bumper

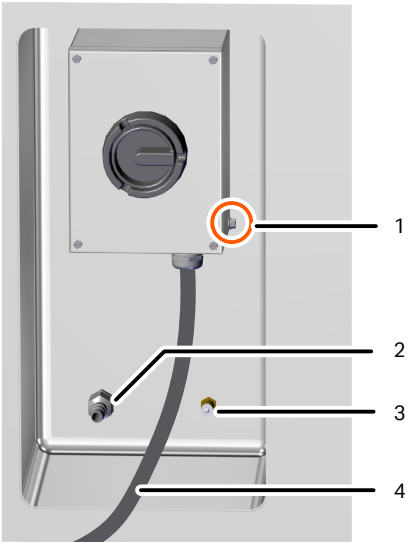
Instrument left side view

The main components visible in the illustration are listed below.

Part	Description
1	Power switch box
2	Power switch
3	Adjustable leveling feet to support the instrument during operation

Connections on the instrument

The illustration below shows a view seen from the left side of the instrument to illustrate pneumatic and electrical connections.



Part	Description
1	Grounding point on the side of the power switch box for vessel bonding, if required
2	Pneumatic connection port for connecting the compressed air supply
3	M12 Ethernet port for connection to the Ethernet box
4	Supplied power cable, not rated for explosive atmospheres

3.4 Instrument components

About this section

This section provides an overview of the components of the instrument.

In this section

3.4.1 Purge and pressurized cabinet

Introduction

WARNING

Explosion hazard. Do not alter the purging system. The purging system is setup and qualified by the manufacturer at delivery and the user must not alter any of its functionality.

If the purging system functionality is altered or is defective, the classification of the system is invalidated and the system must not be used in the potentially explosive atmosphere. Contact your Cytiva representative for advice.

The purge and pressurized cabinet is located inside the instrument enclosure. It contains all electrical components that are not rated for use in explosive atmospheres or hazardous locations. The cabinet is equipped with a purging system, that prevents flammable gases from entering the cabinet. See the following sections for details.

The purge and pressurized cabinet is certified for use in an explosive atmosphere as classified.

Purging functionality overview

The purge and pressurized cabinet is equipped with a purging unit which prevents flammable gases from being present in the cabinet when energized. The purge time is controlled by a digital, pneumatic timer. The purging time is preset before delivery and must not be changed by the user.

During start-up, the purging unit goes into purging mode and removes any flammable gases from the cabinet. Once purging mode is complete it goes into operation mode.

When in operation mode, if the purging unit fails to maintain the specified overpressure in the cabinet, the following happens:

- Any running operations are stopped.
  - Pumps are stopped.
  - Valves are closed.
- Power to the components in the purge and pressurized cabinet is cut.
- The user is notified on the user interface via the system status bar and the ***Alarm*** page.
- The red light on the status indicator is lit.

Purging modes

The purging unit operates in two modes, which are described in the following table.

Mode	Description
Purging	Purging mode is automatically started when the system power switch on the instrument is turned on. The purge air supply must also be turned on for the purge to be successfully completed. During this procedure, a predetermined volume of air under positive pressure is flushed through the cabinet to remove flammable gases remaining in the enclosure. Purging mode is also activated if the pressure in the cabinet falls below the safe threshold. When the purging is completed successfully, the power to the electronics inside the purge and pressurized cabinet is automatically switched on, and the unit goes into operation mode.
Operation	Operation mode is used during normal operation to maintain a certain overpressure in the purge and pressurized cabinet to prevent flammable gases from entering when the system power is turned on. If the pressure in the cabinet drops but stays within the safe range, a warning message appears on the instrument screen. If the purging unit fails to maintain a pressure in the cabinet above the safe threshold, the power supply to the electrical components inside the cabinet is automatically turned off. Any active operations are stopped, and the active formulation is paused. An alarm is automatically activated and the purging unit goes into purging mode. The system cannot start any operations or formulations until the cabinet is re-purged, and the alarm is acknowledged.

3.4.2 Pumps

Peristaltic pump

The peristaltic pump is used to prime the lines of the flow kit.

Centrifugal pumps

The three centrifugal pumps are used to pump the three input fluids through the flow kit.

Each pump is connected to a pump head on the flow kit, and controls the flow of a single input line. The pumps are controlled independently.

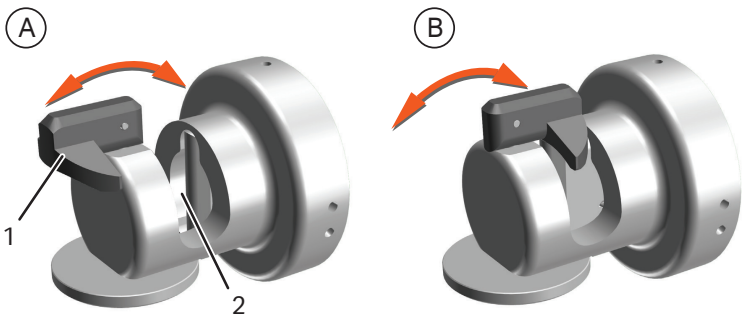
The pump head clips that hold the pump heads in place can be removed for cleaning and exchanged. See *Section 7.5.3 Remove the pump head clips for cleaning, on page 136*.

3.4.3 Valves

Introduction

Pinch valves are used to control the path of the liquid flow through the system. There are seven pinch valves in total. Each valve has a manually operated safety lock. When open, the safety lock prevents the valve from accidentally closing during the installation of the flow kit. When closed, the safety lock holds the tubing in place and allows the valve to close.

The following illustration shows an open (A) and a closed (B) safety lock on a pinch valve.



Part	Description
1	Safety lock (manually operated)
2	Pinch valve opening for tubing

WARNING

Never put fingers or any objects other than the intended tubing into the pinch valve opening.

Input pinch valves

There is one input pinch valve for each of the three input lines, labeled as **XV-001**, **XV-002**, **XV-003**. The valves prevent undesired forward or backward flow through the system.

Output pinch valves

There are two output pinch valves that are used to direct fluid to the waste or formulation collection vessel. The valves are labeled **XV-101** and **XV-102**.

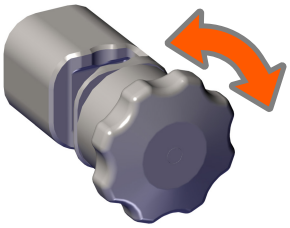
Waste and calibration pinch valves

There are two pinch valves used to direct fluid to either the waste outlet line or to the calibration flow meter during priming and calibration. The waste valve is labeled **XV-201**, and the calibration valve is labeled **XV-202**.

Manual control valve

There is one manual control valve (MCV) on the instrument, labeled **PV-003**. The MCV provides additional flow resistance on the dilution line during calibration and formulation unit procedures. This additional flow resistance compensates for variations between the inlet and outlet vessel heights. The user interface prompts the user to adjust the valve only during the calibration unit procedure.

When turned clockwise, the valve further restricts flow through the line. When turned counter clockwise, the valve allows more fluid to flow through the line.



3.4.4 Meters and sensors

Flow meters

The system is equipped with the following types of flow meters:

1. One calibration flow meter connected to the instrument: a Coriolis flow meter used to calibrate the ultrasonic flow meters.
2. Three ultrasonic flow meters on the flow kit that connect to the flow meter cables on the instrument: used to monitor the flow rates in each input line of the flow kit, and feed the data back to the centrifugal pump control system.

The calibration flow meter can be removed for cleaning or calibration, see *Section 7.5.2 Clean the calibration flow meter, on page 132*.

RFID module

The instrument is equipped with one radio frequency identification (RFID) module. The module reads the RFID tag on the cartridge of the flow kit to determine the flow kit type and the usage status. The flow kit information enables the software to verify that the flow kit installed on the system is suitable for the recipe selected.

3.4.5 Status indicator lights

Introduction

The status indicator lights are located to the right of the user interface on the front of the instrument. There are three LEDs that change color to indicate different system states. Multiple lights can be illuminated at the same time, to indicate multiple conditions.

Part	Description
1	Red/Yellow/Green LED
2	Blue LED
3	White LED

Colors of the status indicator lights

The table below gives a brief description of the meaning of each color of the status indicator lights.

Note: *The system state is also shown on the user interface.*

Light color	System state
Red	Any alarm active
Yellow	Any warning active
Green	Any automatic operation active, or any pump in manual control
Blue	User input is required before a unit procedure can continue
White	No automatic operation is active, and no pump is in manual control, or formulation is paused

3.5 Flow kit

Description

Commercial Formulation System must be used with a flow kit. The table below gives the kit types and usage. Refer to the flow kit *Validation Guide* for detailed descriptions and specifications of the flow kit.

Flow kit	Usage
NxGen commercial development flow kit 12 L/h	• Intended for research use only • Multiple recipes can be run sequentially • Validated for use up to 7 days after the flow kit is first installed[1] • Up to 8.3 hours of formulation run time
NxGen commercial development flow kit 48 L/h	
NxGen commercial manufacturing flow kit 12 L/h	• Intended for use in GMP manufacturing processes • Single-use only • Up to 8.3 hours of formulation run time
NxGen commercial manufacturing flow kit 48 L/h	

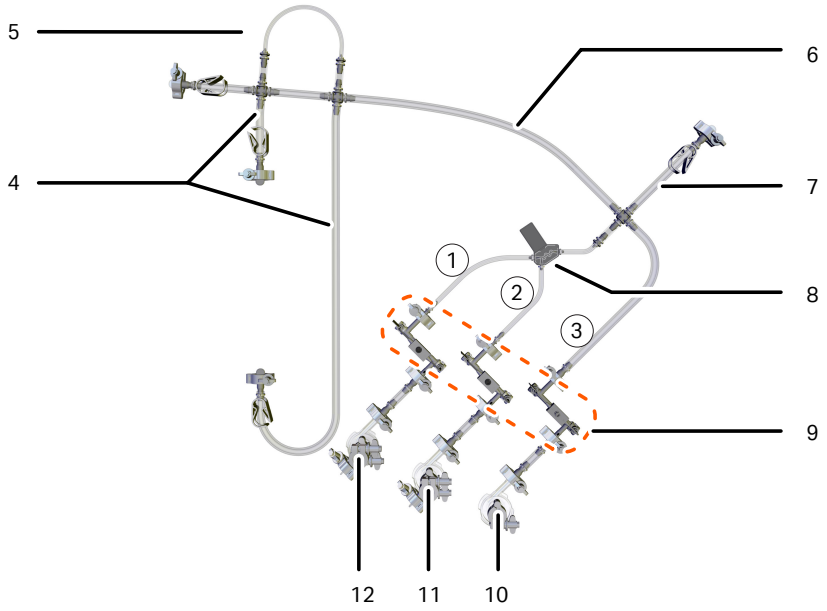
[1] Validated for three installations, with storage in 20% ethanol between runs. Refer to the system *User Manual* for information about storage between runs.

Each flow kit is comprised of the following components:

- A cartridge with a NxGen mixer that combines the payload and the lipid mix, and enables consistent particle formation
- Ultrasonic flow meters that monitor the flow rates for each channel and feed back to the centrifugal pump control
- Pump heads for flow control
- Tubing that serves as a flow path for the input liquids and the output formulation

Note: *The flow kit tubing is a wetted part that must be cleaned according the procedures outlined in* *Section 7.5.1 General cleaning, on page 131*.

Illustration of the flow kit



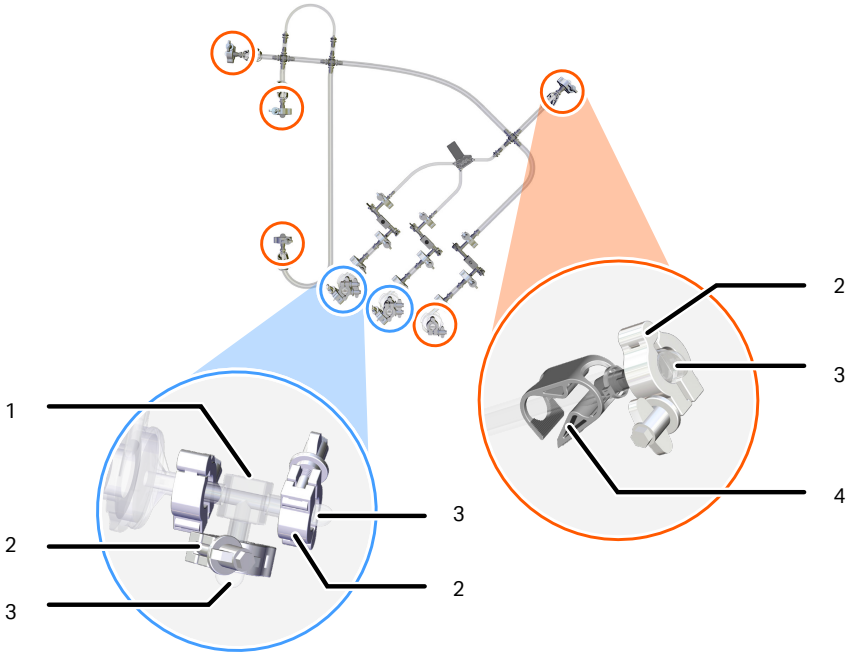
The main components of the flow kit that are visible in the illustration are listed below.

Part	Component	Description
1	Input line 1	Tubing that carries the aqueous input fluid through the flow kit. Installed in valve **XV-001**.
2	Input line 2	Tubing that carries the organic input fluid through the flow kit. Installed in valve **XV-002**.
3	Dilution line	Tubing that carries the dilution fluid through the flow kit. Installed in valve **XV-003** and **PV-003**.
4	Calibration lines	Tubing that carries fluid through the calibration loop during the calibration phase. Installed in valve **XV-202**.
5	Peristaltic pump tubing	Part of the calibration loop tubing that is installed in the peristaltic pump **P-201**.
6	Waste output line	Tubing that carries waste from a procedure to the waste output. Installed in valves **XV-201** and **XV-101**.
7	Product output line	Tubing that carries the formulated product to the product output. Installed in valve **XV-102**.
8	NxGen cartridge	A cartridge with a NxGen mixer that combines the payload and the lipid mix, and an RFID tag that is read by the RFID module on the instrument.
9	Flow meters	Three flow meters that measure the liquid flow rate for each line, using ultrasound. The flow meters are installed in the flow meter housing **FE-001**, **FE-002**, **FE-003**.

Part	Component	Description
10	Pump head 3	Pump head that connects to pump **P-003** on the instrument. The ¾-inch TC connector on the pump head connects to the line for dilution.
11	Pump head 2	Pump head that connects to pump **P-002** on the instrument. The T-connector on the pump head has ¾-inch TC connectors to connect to the lines for formulation fluid 2 and calibration fluid 2.
12	Pump head 1	Pump head that connects to pump **P-001** on the instrument. The T-connector on the pump head has ¾-inch TC connectors to connect to lines for formulation fluid 1 and calibration fluid 1.

Illustration of flow kit connections

Each line of the flow kit has a TC connector to connect to the relevant fluid line. Lines 1 and 2 have T-connectors to enable connection to two different vessel inputs. All TC connections have a cap, as shown in the illustration below.



Part	Description
1	T-connector with two ¾-inch TC connectors
2	¾-inch TC connector
3	Cap

Part	Description
4	Pinch clamp

For information about connecting vessels, see *Section 6.3.3 Connect vessels, on page 110*.

3.6 User interface and control software

Overview

The system has a built in touch-screen user interface and integrated control software.

The integrated software enables the user to:

- Save established processes as recipes
- Update parameters
- Run formulations
- Manually control hardware components
- Change settings
- Access reports and historical run data

Only system operators with adequate authorization can be responsible for designing methods that conform to local SOP and GMP if applicable.

Only personnel with adequate training should be allowed to operate the instrument. Access to system should be controlled by different user-levels with different authorizations.

The system software includes functionality that enables compliance with FDA 21 CFR Part 11.

Description of user roles

The system software includes a user-based access control system. The permitted activities for a user are determined by the user role. It is not possible to edit role permissions individually. There are six pre-defined user roles as follows:

- ***Operators***: General users with access to operation-related controls, excluding manual controls.
- ***Managers***: Advanced users with access to operation-related controls, including manual controls, and permissions to create and approve recipes.
- ***Process Admins***: Administrator role intended for process development.
- ***IT Admins***: Administrator role intended for IT setup and maintenance .
- ***Admins***: Highest level of the administrator role with access to all features of the software.
- ***Auditors***: User access limited to viewing and export records.

All systems are also provided with additional accounts that are only accessible by a Cytiva representative for service.

Permissions for each user role

The following table describes the permitted activity for each user role.

	Operators	*Managers*	*Process Admins*	*IT Admins*	*Admins*	*Auditors*
User management						
Change own passwords	✓	✓	✓	✓	✓	✓
Change passwords of other users	✗	✗	✗	✓	✓	✗
Create, edit, or delete users	✗	✗	✗	✓	✓	✗
Recipe						
Create, copy, or import recipes	✗	✓	✓	✗	✓	✗
View or export recipes to file	✓	✓	✓	✓	✓	✓
Edit unapproved recipe	✗	✓	✓	✗	✓	✗
Edit approved recipe	✗	✗	✗	✗	✗	✗
Promote a recipe (approve recipe)	✗	✓	✓	✗	✓	✗
Demote a recipe (move approved recipe to unapproved)	✗	✗	✗	✗	✗	✗

	Operators	*Managers*	*Process Admins*	*IT Admins*	*Admins*	*Auditors*
Archive a recipe	✗	✗	✓	✗	✓	✗
Operation						
Confirmation of fluid path during installation or uninstallation	✓	✓	✓	✗	✓	✗
Correct a partial install or uninstall during start-up	✓	✓	✓	✗	✓	✗
Manual controls of valves, pumps, and LFM	✗	✓	✓	✗	✓	✗
Manual tools (***Prime line***, ***Fill line***, ***Flush line***, and ***Valve test***)	✓	✓	✓	✗	✓	✗
Create batch plan with unapproved recipes	✗	✓	✓	✗	✓	✗
Create batch plan with approved recipes	✓	✓	✓	✗	✓	✗
Perform all run formulation actions	✓	✓	✓	✗	✓	✗

	Operators	*Managers*	*Process Admins*	*IT Admins*	*Admins*	*Auditors*
Archive batch records (export and delete)	✓	✓	✓	✗	✓	✗
Alarms						
Acknowledge alarms	✓	✓	✓	✗	✓	✗
Enable alarm qualification mode	✗	✓	✓	✗	✓	✗
Settings						
Change settings	✗	✗	✓	✓	✓	✗
Export settings	✗	✗	✓	✓	✓	✓

Documentation

Complete descriptions of the user interface screens, instructions for programming recipes, and instructions for running procedures using the software are provided in the system *User Manual*. See *Section 1.3 Associated documentation, on page 8*.

For detailed guidance on how the audit trail and electronic signature capabilities of the system can help customers to demonstrate 21 CFR Part 11 compliance, please contact your Cytiva representative.

3.7 Accessories

About this section

This section describes accessories available for use with the instrument and the flow kit.

Ethernet box

The Ethernet box is an external accessory to the system, which must be connected in order to transfer data to an external server. The illustration below shows the scale of the Ethernet box in relation to the instrument.

The illustration below shows the electrical connections on the Ethernet box.

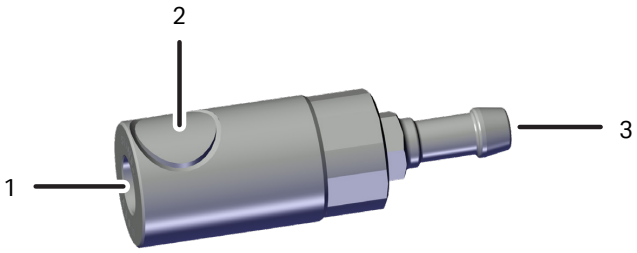
Part	Description
1	M12 Ethernet cable connector for connection to the instrument
2	RJ45 Ethernet cable connector for connection to external computer or network (with cover)
3	Power supply

Barbed connector

The barbed connector is used to connect the air supply tubing to the air supply port on the side of the instrument.

The barb on the connector connects to the user-supplied air supply tubing. A suitable clamp must be provided by the user to hold the tubing in place. The female port of the barbed connector enables quick connection, venting, and disconnection from the air supply port on the instrument.

The illustration below shows the components of the barbed connector.



Part	Description
1	Female connection for the air supply port
2	Release button
3	Barb connection for air supply tubing

Drip tray

The drip tray is an external accessory to the system that fits into the bumper on the front of the instrument. The drip tray collects any drips that spill from the flow kit or instrument components during installation and uninstallation.

4 Installation

In this chapter

About this chapter

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

The initial installation must be done by Service personnel or Application Specialists from Cytiva, or other staff who are authorized by Cytiva to install the system.

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

4.1 Safety precautions

Installing and moving the product

WARNING

The product must be installed and prepared by Cytiva personnel or a third party authorized by Cytiva.

WARNING

Move transport crates. Make sure that the lifting equipment has the capacity to safely lift the crate weight. Make sure that the crate is correctly balanced so that it does not accidentally tip when moved.

WARNING

Heavy object. Because of the significant weight of the product, take great care to avoid squeezing or crushing injuries during movement. Two people are recommended to move the instrument.

WARNING

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

WARNING

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

WARNING

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

WARNING

Explosion hazard. Do not use the power cable supplied with the system in a hazardous location. The supplied cable and cable gland are not rated for use in an environment classified as a hazardous location.

WARNING

All electrical installations must be performed by authorized personnel only.

WARNING

Hazardous voltage. The power switch box must only be opened when the power supply is disconnected and the system has been taken out of operation.

WARNING

Explosion hazard. When working in potentially explosive atmospheres, always use the following to avoid static build up:

- Suitable clothing.
- Non-sparking tools rated for the explosive atmosphere.
- Anti-static cleaning cloths.

CAUTION

Fall hazard. Do not step on the bumper on the front of the instrument. The bumper can break and cause injury to the user.

CAUTION

Make sure that all tubing, hoses and cables are placed so that the risk of tripping accidents is minimized.

CAUTION

The product is designed for indoor use only.

CAUTION

Do not attempt to lift the system by the handles on the left and right sides of the instrument. The handles are for maneuvering the system on the floor, not for lifting.

4.2 Site preparation

Introduction

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

In this section

4.2.1 Delivery, storage and unpacking

Introduction

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

Two people are required to safely unpack the instrument.

For information on how to receive and store the delivery box, and to unpack the instrument refer to the system *Unpacking Instructions* that is attached on the delivery box. It is also available on the web, see *User documentation for Commercial Formulation System, on page 8*.

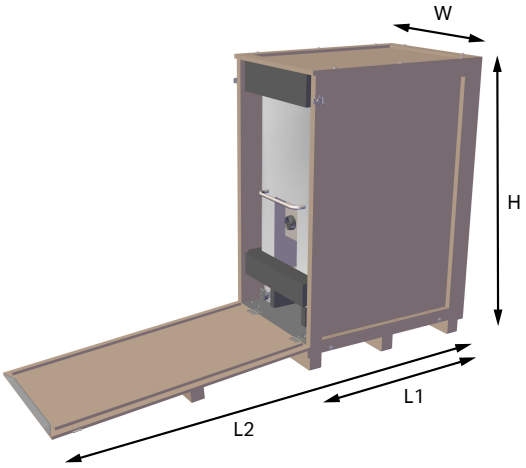
Delivery

Upon delivery, do the following:

- Inspect the crate and packaging for any apparent damage. If damage is found, document, take photographs, and record the damage on the receiving documents. Contact your service representative immediately.
- Move the crate to a protected location indoors.
- Confirm that all items have been received according to the packing list. Note that some accessories are delivered in a separate box.

Dimensions of the crate

The illustration below shows the dimensions and weight of the crate containing the system:



Parameter	Value
W	93.5 cm

Parameter	Value
H	192 cm
L1	139 cm
L2	~331 cm
Weight	400 kg

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	10°C to 30°C
Relative humidity	25% to 65% non-condensing

Transportation

WARNING

Heavy object. Use suitable lifting equipment when moving the unit. All lifting and moving must be performed in accordance with local regulations.

Use suitable lifting equipment, such as a pallet lift or forklift, with a minimum capacity to match the weight of the system plus the transport crate. See the dimensions of the crate, above, and *Dimensions and weight, on page 57* for information about crate weight and system weight. Make sure that the load is evenly distributed over the forks of the lifting equipment.

Note: *Before moving the transport crate, make sure that all openings and apertures that the transport crate is intended to pass through are large enough to allow passage of the transport crate when it is lifted from the floor.*

Read and carefully follow the instructions provided by the labels and symbols on the transport crate. The following table shows symbols that can be found on the transport crate.

Symbol	Meaning
	CAUTION TOP HEAVY. The center of balance is offset and is higher than the center of the crate.
	Fragile
	Keep dry
	This side up
	Recyclable material

Unpacking the system

WARNING
At least two persons are required to unpack the system.

WARNING
Heavy object. The ramp is not reinforced in the center. Do not use a pallet lifter or forklift on the ramp.

WARNING

Heavy object. Because of the significant weight of the product, take great care to avoid squeezing or crushing injuries during movement. Two people are recommended to move the instrument.

WARNING

Tipping risk. When unpacking the product, make sure that the floor surface is level. If the surface is uneven the product can tip over when unloaded.

For information on how to unpack the system refer to the system *Unpacking Instructions*, see *User documentation for Commercial Formulation System, on page 8*.

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.

4.2.2 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 instrument.

Parameter	Value
W	120 cm
D	80 cm
H	170 cm
Weight	270 kg

Space and floor load

For space and floor requirements, see external dimensions and weights in *Section 9.1 Specifications, on page 170*.

In order to allow convenient working conditions for the operator, at least 100 cm of free space should be provided on all sides of the system. Make sure there is sufficient space around the system and the input and output vessels when installed at the intended production location.

Note: *Make sure that the floor can handle the system weight at fully loaded conditions. Observe that for the weight to be equally distributed over all of the feet, the floor must be level and without irregularities.*

4.2.3 Site environmental requirements

Introduction

This section describes the environmental requirements and conditions for installation of the Commercial Formulation System.

CAUTION

The product is designed for indoor use only.

Environmental requirements

The installation site must comply with the specifications given in *Environmental requirements, on page 171*.

Note: *If low flow rates are used on the NxGen commercial 12 L/h flow kit with a fluid at the high or low extremes of the fluid temperature range:*

- *Adjust the ambient room temperature to minimize heat transfer, or*
- *Use insulation where appropriate.*

Refer to the specifications of the flow kit online for details on the fluid temperature range, see *Access user documentation online, on page 9*.

Environmental conditions

The following general requirements must be fulfilled:

- The room must have exhaust ventilation.
- The room must have forced ventilation.
- The products must not be exposed to sources of heat, such as direct sunlight.
- The products must not be exposed to vibrations, strong magnetic or electric fields, and corrosive gas.
- Dust in the atmosphere should be kept to a minimum.

Instrument ventilation

There should be at least 100 cm on all sides of the instrument and above the instrument to allow adequate air circulation.

Heat output

The heat output data is listed below:

- Typically: 200 W
- Maximum: 500 W

4.3 Set up the system

About this section

This section provides required information to set up the system.

In this section

4.3.1 Lower the leveling feet

WARNING
Instrument stability. Leveling feet must be lowered before operation. If the leveling feet are not lowered, the instrument can shift during use, resulting in leakage, damage, or serious injury.

Lower the leveling feet beside the casters to support the system during use. The system must not rest on the casters during operation.

Step	Action
1	Screw the leveling feet downwards using a wrench until the feet touch the floor. 
2	Screw the leveling feet at least two more full rotations. *Result:* The weight of the instrument is transferred completely to the leveling feet and off of the casters.
3	Repeat steps 1 and 2 for the other three leveling feet.
4	Adjust the height of individual feet as needed to make sure the instrument is level. ***Note:*** *It is recommended to verify that the instrument is level with a bubble level applied along the front side and the left side of the instrument.*

Step	Action
5	Screw the locking nut upward until you meet resistance to lock the leveling feet. 
6	Rotate the casters underneath the instrument to keep them out of the way.

4.3.2 Connect compressed air supply to the system

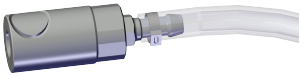
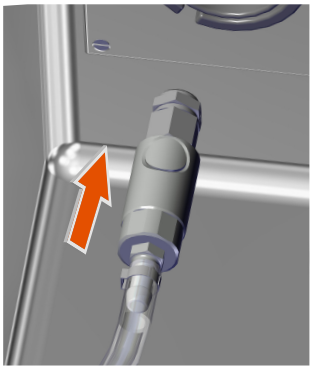
CAUTION

Make sure that correct compressed air pressure is always maintained. Too high or too low pressure can be hazardous and can cause erroneous results and leakage.

This section describes how to connect the compressed air supply. See *Compressed air specifications, on page 171* for requirements of the compressed air supply and tubing connections.

Note: *The system consumes 6.0 to 8.0 SLPM when the air supply is connected, regardless of whether or not the instrument is on. To prevent compressed air consumption when the system is off, install a shut-off valve upstream of the instrument.*

Follow the instructions below to connect compressed air supply to the system.

Step	Action
1	Check that the specified supply of compressed air is available at point of installation.
2	Make sure that the supply gauge pressure to the system is between 6.0 to 8.0 bar g (87 to 116 psig).
3	Connect the air supply tubing to the barbed connector delivered with the system using a hose clamp. 
4	Connect the female tubing connector to the compressed air supply port on the left side of the instrument. 

To disconnect the compressed air supply, see *Section 6.5.3 Depressurize the system and disconnect air supply, on page 123*.

4.3.3 Power supply

Precautions

WARNING

All electrical installations must be performed by authorized personnel only.

WARNING

National Codes and standards (NEC, VDE, BSI, IEC, UL etc.) and local codes outline provisions for safely installing electrical equipment. Installation must comply with specifications regarding wire types, conductor sizes, plugs, branch circuit protection and disconnect devices. Non-compliance can result in personal injury and/or equipment damage.

WARNING

Explosion hazard. When the product is operated or maintained in a hazardous location, it **must be correctly grounded** to avoid static discharge.

WARNING

Hazardous voltage. When energized, the system must always be connected to ground.

WARNING

Hazardous voltage. The power switch box must only be opened when the power supply is disconnected and the system has been taken out of operation.

WARNING

Explosion hazard. Do not use the power cable supplied with the system in a hazardous location. The supplied cable and cable gland are not rated for use in an environment classified as a hazardous location.

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.

Introduction

When the system is used in a non-hazardous environment, the power cable delivered with the system must be installed by Service personnel or Application Specialists from Cytiva.

When the system is used in a hazardous location, authorized personnel must connect a suitable power cable according to the requirements in the following sections.

Power supply requirements

The power supply requirements are specified in *Technical specification, on page 170*, on the system nameplate, and in the documentation package of the delivery.

Also see *Explosive atmosphere certification, on page 186*.

Power supply cable

The following applies for the installation of the power supply cable:

- All electrical installation must be performed by authorized personnel only.
- Follow national and local industrial safety regulations and/or electrical codes for installation.
- The IP boundary for the system stops at the point of entry to the instrument.
- The power supply cable that is shipped with the system must only be used in non-hazardous location environments. For use in a hazardous location, the power supply cable and the associated cable gland must be selected and installed according to local regulations. The factory knockout is sized for a M16 cable gland. This knockout may be enlarged if required for the chosen cable gland. Connect the cable conductors according to the electrical schematics and wiring diagram.
- Refer to the specific requirements for the impacted components for the installation, e.g., min–max conductor cross-section, torque setting, cable gland requirements.
- The integrity of all cable connections must be verified during installation.
- For hazardous locations, the input supply cable gland must be rated for use with an increased safety enclosure as per local regulations, and must have a minimum ingress protection rating of IP 54.

The power cable must be connected in one of the following ways:

- Fixed power supply by means of a permanent connection with an isolation switch.
  - The installation must meet the relevant requirements of national and local industrial safety regulations and be suitable for the application.
  - The isolation switch must always be easy to access.

  - For North America, the isolation switch must be rated for no more than 15 A. For other regions, follow the local regulations on the isolation switch rating requirement based on the current draw requirements and voltage rating of the system.
- Connected with an industrial power plug, compliant with national codes and standards.
  - The power plug must always be easy to disconnect.

Grounding and protective earth

- Follow the grounding and ground impedance requirements of national and local industrial safety regulations and/or electrical codes for grounding of equipment.
- The protective earth wire must be connected to system ground.
- The integrity of all ground connections must be verified during installation, before applying power.
- The integrity of all ground connections must be periodically checked.

Uninterruptible power supply (UPS)

Connecting the system to a UPS can prevent data loss during a power failure, and allow time for a controlled shutdown of Commercial Formulation System.

More information

The documentation package delivered with the system includes the wiring diagrams for the system.

4.3.4 Setup of control system and network

Introduction

This section describes the network connections to be made to and from the system.

Network connections must be made after the mains power is connected.

Control system

Commercial Formulation System is delivered with the control system pre-installed and configured. No specific actions are required with respect to the control system.

Network connection

WARNING

Accessories. Use only accessories supplied or recommended by Cytiva.

System communication interface to a single computer or a network is available via an Ethernet box that is included in the delivery. The Ethernet connection allows transfer of records from the instrument.

The Ethernet port on the instrument is protected by a sealing cover that screws onto the port when it is not in use.

The external Ethernet connection is an intrinsically safe circuit and must only be connected to the provided Ethernet box accessory. Refer to EN 60079-14 for guidance on intrinsically safe cable installation requirements.

Network settings

The system ships with the following network settings:

Parameter	Value
PLC IP	192.168.0.101
HMI IP	192.168.0.102
Subnet mask	255.255.255.0
Default gateway	N/A

A computer-to-instrument connection should use the following as the network settings of the computer:

Parameter	Value
Computer IP	192.168.0.100[1]
Subnet mask	255.255.255.0

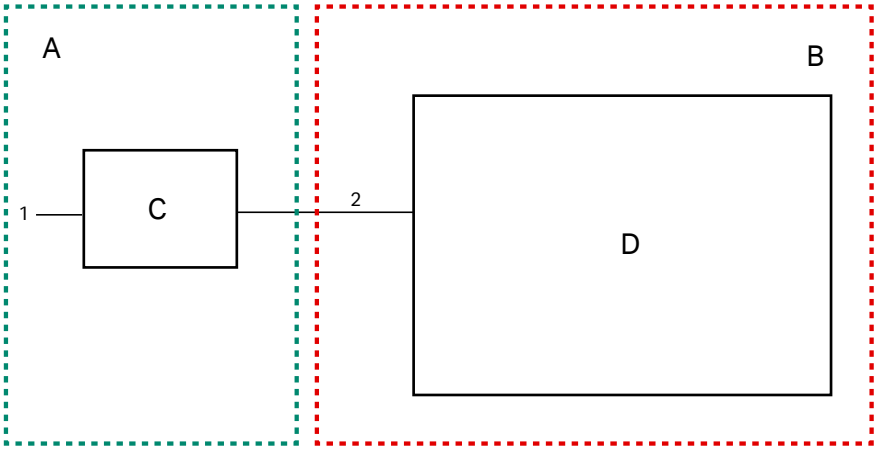
Parameter	Value
Default gateway	Any

[1] Can be any other IP on the same subnet that does not overlap with the PLC or HMI.

A network-to-instrument connection requires the user to modify the HMI and PLC addresses as necessary for the network architecture. Fixed IP addresses are required. See *Section 5.2.3 Modify PLC and HMI settings, on page 80* for instructions on modifying the HMI and PLC IP addresses.

Communication

The illustration and table below describes the communication connections and indicates which system connections must be located in a safe area. The Ethernet box accessory must be located in a non-hazardous location.



Part	Description
A	Non-hazardous area
B	Hazardous area
C	Ethernet box
D	System
1	RJ45 Ethernet port
2	M12 Ethernet port on the instrument to Ethernet port on the Ethernet box

For illustrations of the parts and the connection points on the system, see *Connections on the instrument, on page 28*. For illustrations of the parts and connections on the Ethernet box, see *Ethernet box, on page 45*.

OPC UA client operation

The system can be connected to an open platform communications (OPC) unified architecture (UA) client to enable remote system monitoring. The OPC UA communications take place over the Ethernet connection cable alongside any other traffic. The Ethernet box must be connected to the instrument and the external network (or OPC UA client) for the communications to take place.

The following table gives the parameters required to set up the connection on the external OPC UA client.

Parameter	Value
Method	`OPC TCP`
IP address	`192.168.0.101` (PLC)
Port	`4840`
Available security options (policy-mode)	`Basic256Sha256-Sign`
	`Basic256Sha256-Sign&Encrypt`
User authentication	Contact your Cytiva representative for the required username and password combination.
OPC UA variables	Contact your Cytiva representative for available variables and their configuration. An OPC UA Nodeset File is available upon request.

A certificate for the PLC OPC UA server is available upon request. Contact your Cytiva representative.

4.4 Moving the system

Introduction

This section provides instructions for moving the system to another location by rolling it on the integrated casters.

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.

Prepare to move the system

WARNING

Heavy object. Because of the significant weight of the product, take great care to avoid squeezing or crushing injuries during movement. Two people are recommended to move the instrument.

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.

WARNING

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

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

Before moving the system, make sure that the new location fulfils the site requirements (see *Section 4.2.2 Room requirements, on page 57* for space requirements).

Follow the instructions below to prepare Commercial Formulation System for moving.

Step	Action
1	Disconnect any fluid vessels, and remove any flow kit installed on the system (see *Section 6.5.1 Uninstall the flow kit, on page 114*).
2	Shut down the instrument (see *Section 6.5.2 Shut down the system, on page 122*).

Step	Action
3	Disconnect the air supply from the instrument.
4	Disconnect all communication cables from the instrument.
5	Disconnect the mains power cable.

WARNING
Shock hazard. If the power cable is hard wired into the power switch box, disconnection must be performed by authorized personnel only.

WARNING
Explosive atmosphere: Ignition hazard. Do not disconnect the mains power cable in an explosive environment without first connecting an external grounding wire. The system is ungrounded without the power cable connected and can be a spark source.

6	Raise the leveling feet using a wrench so that the system rests on the casters.

Moving the instrument

The system can be rolled on hard and level surface that is clean and smooth. Use the handles on the sides of the instrument to guide the system.

If the floor quality does not allow rolling the system on the casters, or if the floor is dirty or coarse, the system can be moved with a pallet jack or fork lift.

Note: *Before moving the system, make sure that all openings and apertures that the system is intended to pass through are large enough to allow passage of the system when it is lifted from the floor.*

Re-install the system at a new location

Follow the instructions below to re-install the system at the new location. If the system has been moved by lifting, or repacked in a crate during transport, contact Cytiva to re-qualify the system for use in the new location.

Step	Action
1	Lower the leveling feet to remove the weight from the casters and compensate for any unevenness in the floor surface. See *Section 4.3 Set up the system, on page 60*.
2	Reconnect the mains power cable. See *Power supply cable, on page 66*.
3	Reconnect the air supply and communication cables as in *Section 4.3.2 Connect compressed air supply to the system, on page 63* and *Section 4.3.4 Setup of control system and network, on page 68*.

5 Preparation

About this chapter

This chapter provides information on how to prepare the system for operation.

In this chapter

5.1 User management

The system is supplied with a default account and password for each user role for the initial start-up and login.

The ***Admin/User settings*** screen is intended for managing user accounts. All active user accounts are listed on this screen. Depending on the user role, the number of visible accounts on the screen is different. Only visible accounts can be modified. An ***Admin*** user can view all active user accounts. An ***IT Admin*** can view other user accounts, except the ***Admin*** account. All other user accounts can only view their own account.

For more information on the permitted activities for each user roles, see *Permissions for each user role, on page 42*.

Default user account

The system is provided with default user accounts for the six different user roles. The passwords for all default user accounts, except for the ***Admin*** account, expire in 90 days. All user accounts, except for the ***Admin*** account, are intended for training purposes, and new user accounts must be created before operating the procedure. The system prompts the user to change the password for the new user account at first login.

The system is provided with the following default user accounts:

User role	Login detail
Admin	User Name: `admin` Password: `abcdef7*`
Operator	User Name: `example_operator` Password: `password1!`
Manager	User Name: `example_manager` Password: `password1!`
Process Admin	User Name: `example_process_admin` Password: `password1!`
IT Admin	User Name: `example_it_admin` Password: `password1!`
Auditor	User Name: `example_auditor` Password: `password1!`

Password requirements

The following password restrictions apply when logging in to the instrument:

- Password minimum length is eight characters.
- Password must contain the following:
  - At least one non-alphabetical characters, for example, !, $, #, %, and
  - At least one number (0 through 9).
- Password expires after 90 days, except for the ***Admin*** account.
- Up to five incorrect login attempts are allowed before a user account is set as unauthorized.

  Note: *An admin user must log in and revert the unauthorized user account.*

Change password

Follow the steps below to change the password of your user account.

Step	Action
1	Tap ***Admin*** → ***User settings***
2	Tap the password column of your user account *Result:* An on-screen keyboard and a ***Change password*** pop-up appear.
3	Enter a new password. For more information on the password requirement, see *Password requirements, on page 75*.
4	Tap ***OK***. *Result:* The password is automatically saved.
5	Tap ***Alarms*** →***Event Log*** and confirm that there were no messages related to the new password, i.e., password too short, password already in use, etc.

5.2 Settings

In this section

5.2.1 Change date and time

Changing the system time will cause a discontinuity in the data log, event log, and audit trail. If required, export or archive the system logs before changing the system time.

Follow the instructions below to change the date and time.

Step	Action
1	Make sure there is no batch active.
2	Tap the ***Admin*** button to open the ***Admin/Sytem settings***screen.
3	Enter the new date and time in the ***Set display time*** field. ***Note:*** *Use the format MM/DD/YYYY hh:mm:ss AM/PM to enter the new date and time.*
4	Tap ***Change time*** to apply the new date and time. *Result:* The date and time at the top of the screen are immediately updated.

5.2.2 Change timezone

Follow the instructions below to change the timezone

Step	Action
1	Tap the ***Admin*** button to open the ***Admin/Sytem settings***screen.
2	Enter the new time zone information in the ***Set display time zone*** fields: a. Select the time zone from the drop-down list. b. Optional. Check the ***Enable automatic daylight savings*** box. If daylight savings are enabled, set the daylight savings offset in minutes. Set the dates and times when the daylight savings offset is applied.
3	Tap ***Change timezone*** to apply the new time zone and DST settings. *Result:* The time at the top of the screen is immediately updated.

5.2.3 Modify PLC and HMI settings

Introduction

If the system is connected to a network, the PLC and HMI IP addresses might need to be modified to match the local network subnet. The following sections describe the procedure to modify the IP address and subsequently verify the PLC-HMI connection.

Exit the HMI runtime environment

Step	Action
1	Start up the system as described in *Section 6.2.1 Start the system and software, on page 87*.
2	On the user interface, tap ***Admin*** →***Settings***
3	Tap ***Exit runtime***. *Result:* The system's underlying desktop is shown.
4	On the ***Start Center*** menu, tap ***Settings***.

Set the PLC IP address

After exiting the runtime, follow the steps below to modify the IP address of the PLC.

Step	Action
1	From the ***Settings*** screen, tap ***Service & Commissioning***. *Result:* The ***Service & Commissioning*** dialog appears.
2	Open the ***IP Config*** tab from the top right of the dialog.
3	Tap ***Assign IP***.
4	From the menu bar, tap ***Settings*** →***Interface***.
5	Make sure that the ***X1*** port is selected for the HMI.
6	From the menu bar, tap ***Network*** →***Scan*** →***Start***. *Result:* The network scan begins. The scan takes less than one minute. The PLC IP address appears on the screen after the scan is complete as long as its base IP address is on the same subnet as the HMI, and there are no other devices with the same IP address as the PLC on the network. The value in the ***Type*** column is `S7-1200`.

Step	Action
7	Tap the PLC item in the list, and modify the following as required: • ***IP Address*** • ***Subnet Mask*** • ***Default Gateway*** ***Note:*** ***Default Gateway*** *is optional and can be left blank.*
8	With the PLC item in the list still selected, tap the menu bar, then tap ***Device*** →***Download*** →***All***.

Set the HMI IP address

After exiting the runtime, follow the steps below to modify the IP address of the HMI.

Step	Action
1	From the ***Settings*** screen, tap ***Network and Dial-up Connections***.
2	Double-tap ***PN_X1***.
3	In the ***IP Address*** tab of the ***PN_X1 Settings*** dialog, tap ***Specify an IP address***.
4	Modify the following as required: • ***IP Address*** • ***Subnet Mask*** • ***Default Gateway*** ***Note:*** ***Default Gateway*** *is optional and can be left blank.*
5	Tap ***OK*** when finished.

Update the HMI-PLC connection

After changing either the PLC or HMI IP address, the HMI-PLC connection must be updated following the steps below.

Step	Action
1	From the ***Settings*** screen, tap ***Service & Commissioning***. *Result:* The ***Service & Commissioning*** dialog appears.
2	Open the ***IP Config*** tab from the top right of the dialog.

Step	Action
3	Tap ***Set Connection***. *Result:* The expected connection to the PLC (`HMI_Connection_1`) is shown in the ***Set Connection*** dialog.
4	Select the connection name and modify the ***IP Address*** field to be the same as the new IP address of the PLC.
5	In the upper left of the dialog, tap ***Save***.

Verify HMI-PLC communication

After modifying one or both IP addresses, follow the steps below to verify the communication is successful between the HMI and the PLC.

Step	Action
1	Close all open dialog boxes.
2	On the ***Start Center*** menu, tap ***Start*** *Result:* The HMI runtime starts and the log in screen of the user interface screen appears.
3	Log in to the instrument as described in *Start the software, on page 88*. *Result:* The ***Home*** screen appears within a few seconds if the PLC-HMI connection is working. If the start up screen shows ***Establishing internal communications*** for longer than 30 seconds, there is a problem with the PLC-HMI connection.
4	If there is a problem with the PLC-HMI connection, tap ***Exit*** to exit the runtime. Check and fix any incorrect PLC and HMI IP address settings.

6 Operation

About this chapter

This chapter gives instructions on how to operate the Commercial Formulation System 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.

WARNING

Explosion hazard: Never open panels and access doors on the instrument when the instrument is energized in a potentially explosive atmosphere.

WARNING

Pressurized system. Do not open any fluidic connections unless the flow kit is depressurized. If the fluidic connections are opened while the system is in a pressurized state, the equipment may be damaged and personal injury or death may occur.

WARNING

Crush risk. Do not touch any part of the peristaltic pump while the pump is running.

WARNING

Never put fingers or any objects other than the intended tubing into the pinch valve opening.

CAUTION

Make sure that correct compressed air pressure is always maintained. Too high or too low pressure can be hazardous and can cause erroneous results and leakage.

CAUTION

Pinch hazard. Be careful to avoid squeezing or crushing injuries when installing tubing in pinch valves.

6.2 Prepare the system for a procedure

About this section

This section describes the steps that must be performed to prepare the system for a batch formulation.

In this section

6.2.1 Start the system and software

Start the system

Follow the steps below to start up the instrument.

Step	Action
1	Verify that the compressed air supply volume and pressure meet the specifications for compressed air supply to the system. See *Compressed air specifications, on page 171*. ***Note:*** *Lack of compressed air during a run can jeopardize the run.*
2	Make sure that all panels and access doors are closed and sealed correctly to maintain the ingress protection rating.
3	Check that air is connected to the pneumatic air supply according to the instructions in *Section 4.3.2 Connect compressed air supply to the system, on page 63*.
4	Turn on power to the system by turning the power switch to the ON position (**I**).  *Result:* The user interface starts up and the purge cycle begins, which can last up to 60 seconds. When purging is complete, all electrical components inside the purge and pressurized cabinet turn on. The user interface can take up to one minute to start up. When the system is fully functional, the ***Log in*** screen is shown.

Start the software

Follow the steps below to start and log in to the software.

Step	Action
1	Tap the ***User name*** input field. *Result:* The on-screen keyboard appears.
2	Enter your username and then tap the return key. Follow the same process to enter your password in the ***Password*** input field. ***Note:*** *The initial log in must use one of the default username and password. See* *Default user account, on page 75* *for details.* ***Tip:*** *Tap the eye icon to show the password.*
3	Tap ***Log in***. *Result:* The ***Home*** screen appears on the display. If the user logs in with a new account or the password has expired, the software prompts the user to change the password. See *Change password, on page 76* for details on changing a password.

6.2.2 Prerequisites and required materials

Required materials supplied by Cytiva

- Commercial Formulation System instrument
- NxGen flow kit that is compatible with the chosen recipe. See *Section 3.5 Flow kit, on page 37* for information about flow kit types.

  Note: *Flow kits must be ordered separately from the instrument. See* *Section 9.5 Ordering information, on page 187*.
- 4 mm hex wrench
- 7/8-inch open ended wrench

Required materials supplied by the user

WARNING
Explosion hazard: Static buildup. Only use fluids with conductivity greater then 10 000 pS/m. Using low conductivity fluids can result in static buildup.

The following table gives the required materials that must be supplied by the user.

Required material	Description
Input fluids[1]	Aqueous buffer for priming and calibrating
	Payload for formulation
	Solvent for priming and calibrating
	Lipid mix for formulation
	Dilution buffer for diluting, if applicable for chosen recipe
Input vessels[2]	Up to five vessels (biocontainers, single use mixers, or stainless steel tanks with TC adaptors): one for each input fluid, sized based on the recipe parameters. See *Input vessel sizing, on page 92* for vessel sizing recommendations
Output vessels[2]	Waste output vessel, sized based on the recipe parameters
	Product output vessel, sized based on the recipe parameters
Tubing	Tubing for connecting the input and output vessels to the system

Required material	Description
Tubing connectors[3]	¾ inch hygienic (TC) connectors for connecting input and output vessel tubing to the flow kit
Shut-off valves or pinch clamps	Every connected vessel must have an independent shut-off valve or pinch clamp on the tubing line close to the point of connection with the flow kit
Flow elements	Any additional flow elements needed to connect the vessels to the system

[1] For temperature and viscosity specifications of the fluids, refer to the flow kit documentation online, see *Access user documentation online, on page 9*. Running a cold fluid can result in condensation on the outer walls of the flow kit, depending on the ambient conditions.
[2] Material compatibility must be evaluated for each formulation.
[3] Adaptor assemblies can be used as needed, as long as the pressure drop in the line does not exceed the limitations in *Pressure drop limitation, on page 91*.

6.2.3 Vessel set up

Introduction

WARNING

Risk of leakage. Make sure the collection vessels are dimensioned for the maximum possible volume, according to the specifications in this document. Undersized vessels could overflow and leak flammable liquid and cause an ignition hazard.

WARNING

Explosion hazard. Fluid vessels holding flammable liquids must be secured and sealed to prevent exposure of the fluid to the environment.

The user is required to supply up to seven different vessels when using the instrument including:

- Calibration input 1
- Calibration input 2
- Formulation input 1
- Formulation input 2
- Dilution input
- Waste output
- Product output

Pressure drop limitation

The sum of the maximum pressure drop on the inlet line and the maximum pressure on the outlet line must not exceed 0.2 bar (0.02 MPa, 3 psi) at the total flow rate set for the specific recipe.

In addition, the pump inlet pressure must not be less than 0.945 bar absolute (0.0945 MPa, 13.7 psi) when accounting for the following:

- Component losses before the pump (for example, tube and valves)
- The atmospheric pressure reduction at the given elevation
- The minimum liquid levels in the input vessels

Any restrictions (such as valves, elbows, etc.) that are part of the inlet lines must be placed as far as possible from the pump inlets on the system, with a recommended minimum distance of 10 times the inlet line diameter.

The pressure drop on the inlet lines can be calculated based on the maximum flow rate through the inlet line. The pressure drop on the outlet lines must be determined at the maximum total flow rate.

Input vessel sizing

The input vessels must be sized to hold the fluid volumes required by the recipe, and any manual priming, calibration, or flushing procedures. The recommended minimum sizes for the input vessels are given in the table below.

Note: *The recommended vessel sizes are conservative, to allow for additional fluid requirements above the fluid used in the automated procedure. The user must validate the size of the vessels used for each procedure.*

To calculate the required fluid volumes based on the recipe parameters, refer to the system *User Manual*, see *User documentation for Commercial Formulation System, on page 8*.

Fluid line	Recommended minimum vessel volume
Calibration fluids 1 and 2	2 L
Formulation fluids 1 and 2	0.5 L greater than recipe volume[1]
Dilution fluid	NxGen 12 L/h: • 1:1 dilution ratio: 5 L greater than recipe volume • 10:1 dilution ratio: 20 L greater than recipe volume
	NxGen 48 L/h: • 1:1 dilution ratio: 10 L greater than recipe volume • 8:1 dilution ratio: 30 L greater than recipe volume

[1] The volume recommendation does not account for the volume required to prime the line from the vessel to the T-connector on the flow kit. The vessel must be sized appropriately to hold additional fluid required to prime the vessel lines.

Output vessel sizing

The output vessels must be sized to accommodate the input volumes.

Use the following calculation to determine the minimum vessel size that is required for the product output vessel.

$V_P = 1.05 \times V_R$

Where,

V_P is the recommended volume for the product output vessel, and

V_R is the volume of formulated product defined in the recipe.

Use the following recommendations for the waste output vessel.

Scenario	NxGen commercial flow kit 12 L/h	NxGen commercial flow kit 48 L/h
No dilution	5 L	5 L
Dilution	20 L	30 L

Note:
- *These are conservative recommendations that account for the possibility of large priming and calibration volumes. Actual waste volumes may be as low as 40% of the recommended waste vessel volume.*
- *The recommendations above assume a single batch. There must be sufficient capacity in the waste vessel when starting subsequent batches with the same flow kit (if allowed). Otherwise, the waste vessel must be emptied or replaced between batches.*

Vessel placement at ≤ 600 m elevation

The following table gives the height limitations for the vessels when the system is used at elevations at or below 600 m. The liquid levels in the input vessels must fall within the minimum and maximum heights in the table, regardless of the vessel used. The output vessels are initially empty, and must also be placed within the height range listed in the table below.

Note: *All heights are measured from the floor.*

Parameter	Specification
Maximum height of the input fluid level	1.6 m
Maximum height of the output vessel	1.6 m
Minimum height of the input fluid level	0.5 m
Minimum height of the output vessel	0.5 m

Use the height indicators on the right side of the instrument to assist in setting up the vessels at the correct heights.

Follow the recommendations below for setting up the fluid vessels.

- For low flow calibration, avoid placing the waste output vessel significantly higher than the calibration input vessels. This can result in difficulties calibrating. For troubleshooting calibration failures for an active procedure, see *Chapter 8 Troubleshooting, on page 139*.
- A calibration setup that is similar to the starting formulation setup provides the most reliable calibration results. It is recommended that the fluid height of the formulation and calibration input vessels are similar, with a starting fluid height above or level with the product output vessel.
- Waste and product output vessels are recommended to be at similar levels before the start of a batch formulation.
- When working with flammable liquids, it is recommended that at least one of the input vessels or the product output vessel is grounded.

Vessel placement at > 600 m elevation

When operating at altitudes above 600 m, the vessel configuration must be modified to make sure that the pump inlet pressure is not less than 0.945 bar absolute (0.0945 MPa, 13.7 psi). Modify the vessel configuration in one of the following ways:

1. For any vessel, increase the minimum liquid level. The vessel height must remain within the maximum allowable height.
2. Increase the minimum and maximum liquid levels for all vessels while maintaining a maximum difference in fluid levels between any two vessels of 1.1 m.

For more information about the atmospheric pressure reduction, see *Pressure drop limitation, on page 91*.

6.3 Run a procedure

Introduction

This section gives an overview of the workflow for running a procedure on the system, as well as information about how to make the connections between the kit, fluid vessels, and the instrument.

For detailed steps about initiating a procedure on the user interface, refer to the system *User Manual*, see *User documentation for Commercial Formulation System, on page 8*.

In this section

6.3.1 Workflow

The table below describes the unit procedures that make up the formulation procedure. Refer to the system *User Manual* for detailed instructions on how to run a procedure using the software, see *User documentation for Commercial Formulation System, on page 8*.

Step	Name	Description of unit procedure
1	***Install***	Installing the flow kit: • Opens valves to allow flow kit installation. • Verifies that the kit can be installed based on the unique RFID tag identifier.
2	***Batch plan***	Setting up the batch plan: • Prompts the user to set the batch label. • Allows the user to select a previously defined formulation recipe. • Verifies that the flow kit is appropriate for the selected formulation recipe.

Step	Name	Description of unit procedure
3	***Prime***	Priming the system with empty reagents and buffers: • Sets the ultrasonic flow meters to the calibration kinematic viscosities set in the recipe. • Directs the user to prime the reagent line (if there is a T-connector) until the line and T-connector are primed. This operation uses the peristaltic pump and valve toggling. • Directs the user to prime the reagent buffer line (or dilution line) until the line and the ultrasonic flow meter are primed. This operation uses the peristaltic pump and valve toggling. • Runs an auto prime to clear the rest of the line. This uses the peristaltic pump, the centrifugal pumps, and valve toggling. • For the dilution line, a larger flush is done to clear the remaining air up to valves **XV-101** and **XV-102**. • Resets the ultrasonic flow meters to zero. • Prompts the user to open the pinch clamps on the calibration line. • Primes the calibration line. • Prompts the user to check for bubbles.
4	***Calibrate***	Calibrating the flow meters: • Guides the user in setting the manual control valve on the dilution if required. • Runs each centrifugal pump independently at a fixed fill flow rate to fill the calibration flow meter with the target fluid. • Runs each centrifugal pump independently at a fixed calibration flow rate to calibrate the ultrasonic flow meters to the calibration flow meter. • Runs all pumps together at the target flow rate to verify the mixing parameters for the recipe are reachable.

Step	Name	Description of unit procedure
5	***Formulate***	Formulating the product: • Instructs the user to close the buffer lines and open the reagent line. • Sets the ultrasonic flow meters to the formulation kinematic viscosities set in the recipe. • Runs the pumps with the target of flushing at least 100 mL of reagent through each pump. • Switches from waste to formulation. • Runs formulation until the recipe volume is reached. • Instructs the user to close and save the batch.
6	***Uninstall***	Uninstalling the flow kit: • Allows an optional flush of the flow kit with calibration fluids before uninstalling. • Guides the user to remove the flow kit. • Allows an optional drain of the calibration flow meter. • Valves open to allow flow kit removal.

Note: *During normal operation, there is 200 mL of solvent (from input line 2) in the flow path at any given time. The solvent concentration changes from 100% to less than 50%,depending on the fluids used and recipe parameters, as the fluid moves through the system.*

6.3.2 Install flow kit

Introduction

The flow kit installation must be performed when prompted by the software. The following sections describe how to connect the flow kit to the instrument. The flow kit installation begins at the top left of the instrument, and proceeds down the front of the instrument.

IMPORTANT
Do not tap ***Continue*** on the user interface until all steps in this section are completed.

Verify and open the kit

NOTICE
Kit damage. Do not pull on connections. Make sure that the kit components do not get caught on and pulled by other system components.

NOTICE
Compromised flow kit integrity. If the flow kit integrity cannot be verified, do not use the kit and contact Cytiva.

Before opening the flow kit, perform a visual inspection of the flow kit to be used and check the following:

- Verify that the irradiation indicator on the product label is red.
- Verify that the inner bag that holds the flow kit is intact and has not been torn.

Follow the steps below to open the kit and finish the verification.

Step	Action
1	Open the packaging and remove the kit. ***Note:*** *The flow kit is fully assembled, with caps on each input and output opening.*
2	Remove the steel discs from the pump heads and dispose of them according to local regulations.

Step	Action
3	Verify that the cartridge label lists the same type of NxGen cartridge as the flow kit name on the outer packaging label.
4	Inspect the NxGen cartridge, pump heads, flow sensors, and tubing for visible damage.
5	Verify that all input and output TC connectors are capped.
6	Orient the flow kit so that the calibration loop is on the left side, with the peristaltic pump tubing at the top.

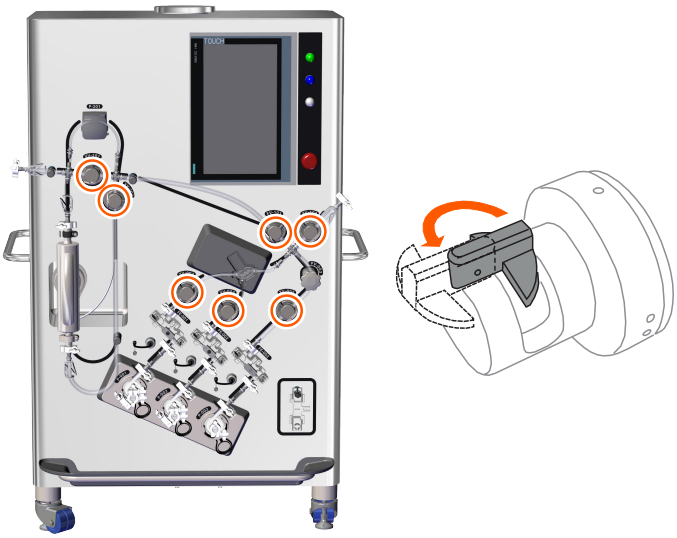
The flow kit is now ready for installation.

Install flow kit components

CAUTION
Pinch hazard. Be careful to avoid squeezing or crushing injuries when installing tubing in pinch valves.

When prompted by the software, follow the steps below to install the tubing, cartridge, flow meters, and pump heads on the instrument.

Step	Action
1	Open the safety locks on all seven pinch valves. Move the black lever on the pinch valves 180 degrees.

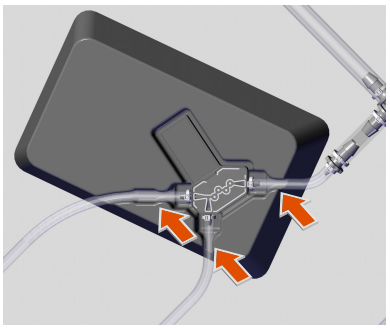


2	Open the peristaltic pump and press the peristaltic pump tubing into the peristaltic pump opening.

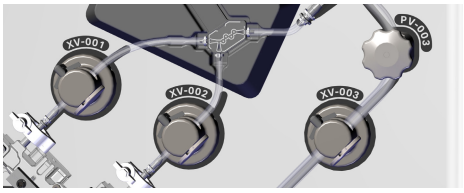
NOTICE
Kit damage. Make sure the peristaltic pump tubing is fully inserted before closing the pump. If the pump cover pinches the tubing, the tubing can be damaged.

Step	Action
3	Close the peristaltic pump. 
4	Place the waste output line into the waste pinch valve **XV-201**. Make sure the tubing is supported by the tube supports on the instrument. 
5	Place the right side of the waste output line into the output valve **XV-101**, and the product output line into the output valve **XV-102**. 
6	Place the NxGen cartridge in the cartridge holder.

Step	Action
7	Press each line connected to the cartridge into the retention features of the cartridge holder.

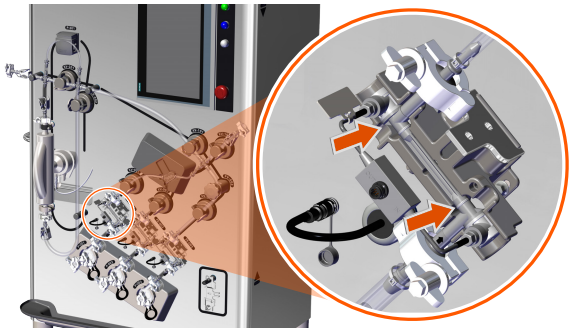


8	Place the three input lines into the corresponding valves: • Formulation line 1 into valve **XV-001** • Formulation line 2 into valve **XV-002** • Dilution line into the MCV **PV-003** and valve **XV-003**



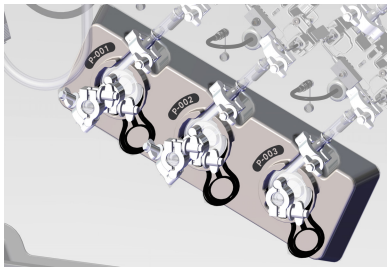
9	Press the body of each flow meter into its respective flow meter housing firmly with two hands. Install: • Flow meter 1 on input line 1 into the housing **FE-001**. • Flow meter 2 on input line 2 into the housing **FE-002**. • Flow meter 3 on the dilution line into the housing **FE-003**.

Step	Action

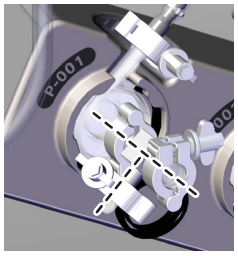


10 Press the pump heads on the input lines into their respective pumps until you hear a click. Install:

- Pump head 1 on input line 1 into pump **P-001**.
- Pump head 2 on input line 2 into pump **P-002**.
- Pump head 3 on the dilution line into pump **P-003**.



11 Make sure the T-connectors on pump **P-001** and **P-002** are pointing down and to the left, as shown in the illustration below. If necessary, make adjustments to the position to match the illustration.

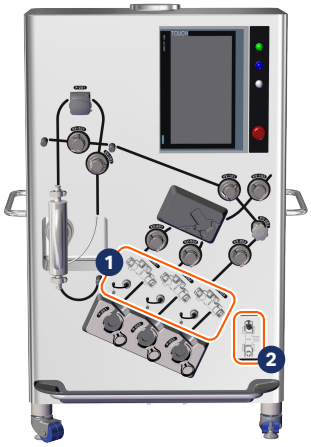


Connect the flow meter cables

> **WARNING**
> **Explosion hazard: Active connections.** Do not connect or disconnect electrical cables to the flow meters outside the ***Install*** and ***Uninstall*** unit procedures. Connections must not be made or broken while there is power to the connection.

Follow the steps below to connect the flow meter cables.

Step	Action
1	Identify the flow meter housing and flow meter cables connected to the instrument (1) and the flow meter covers (2).

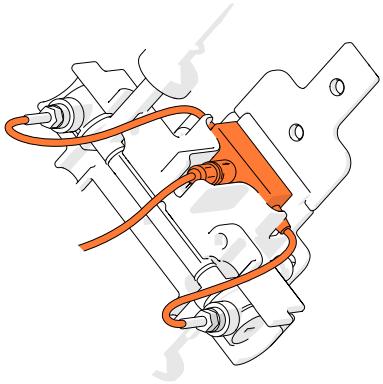


2	Disconnect the cable from the dummy connector.
3	Cap the dummy connector.

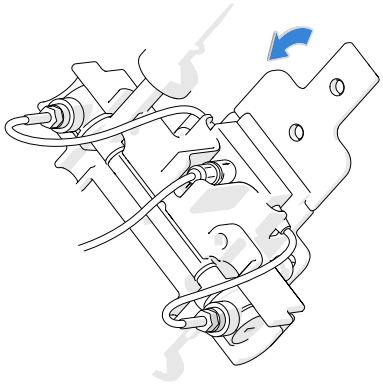
4	Plug in the flow meter cable as follows: **a.** Align the arrows on both connectors.

Step	Action
	b. Press the connectors together firmly.

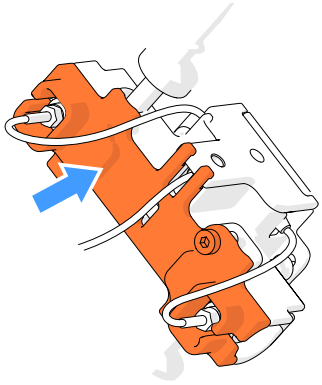
5	Lift the flap on the flow meter housing.
6	Place the flow meter connector into the back compartment of the flow meter housing. Make sure the flow meter cable rests in the groove in the front of the housing.



Step	Action
7	Close the flap on the flow meter housing.

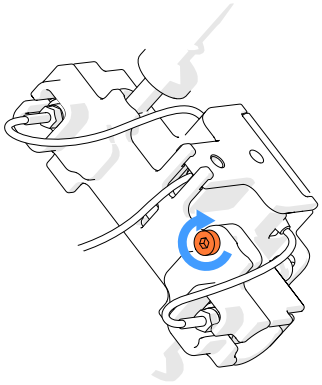


8	Take a flow meter cover from the cover holder at the bottom right of the instrument.
9	Place the flow meter cover on the flow meter housing with the hooks on the cover towards the instrument. Make sure the flap is held in place by the hooks on the flow meter cover.



Step	Action
10	Tighten the screw on the flow meter cover with a 4 mm hex wrench until you meet resistance. Then tighten approximately ten degrees more.

NOTICE
Hardware damage. Do not over-tighten the screw.



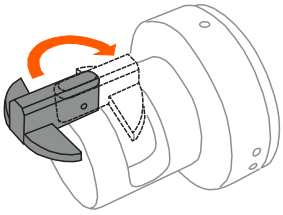
11	Repeat steps 2 to 10 for each flow meter.

WARNING
Explosion hazard. For the explosive atmosphere classification of the control unit to qualify, all flow meter covers must be secured when the connections are powered.

Finish flow kit installation

After connecting the flow meter cables, follow the steps below to connect the lines of the calibration loop and complete the flow kit installation.

Step	Action
1	Open the TC clamps on the calibration lines and remove the caps covering the lines. Make sure the gaskets remain on the flow kit lines when removing the caps.
2	Store the caps in a safe location.

Step	Action
3	Connect the calibration lines to the calibration flow meter using the TC clamps. 
4	Guide the right calibration line into valve **XV-202**.
5	Turn the black levers on the pinch valves 180 degrees to close the safety locks on all pinch valves: 
6	Make sure all four pinch clamps on the flow kit are open before proceeding.

The flow kit is now installed and ready for vessel connections. Follow the instructions on the user interface.

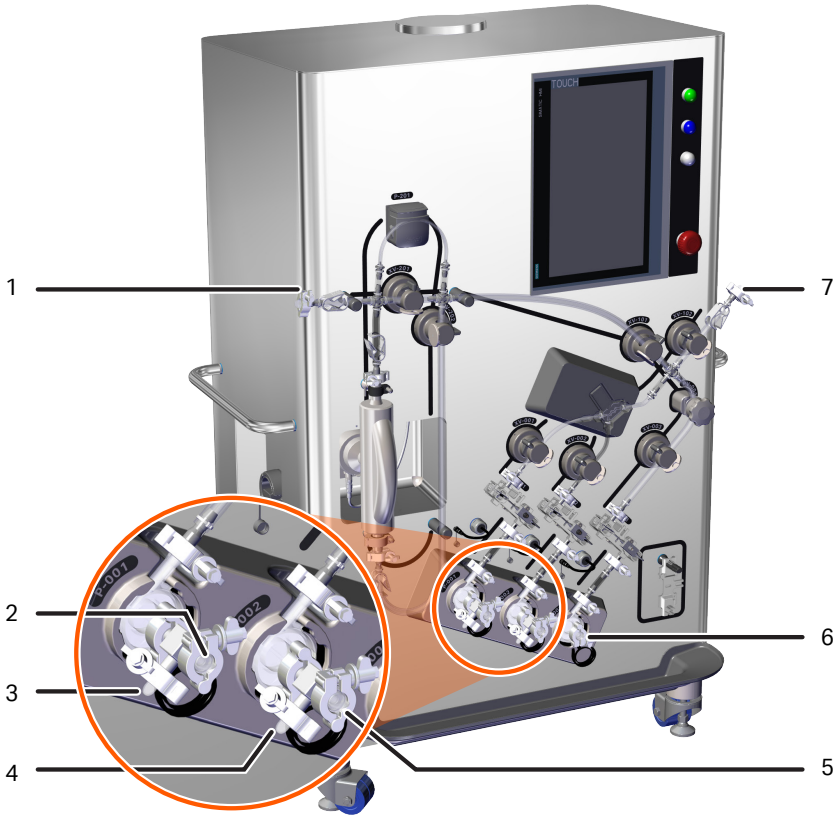
6.3.3 Connect vessels

Introduction

The following section describes how and where to connect the input and output vessels after the flow kit has been installed on the system.

Vessel connection points

The illustration below shows where each vessel must be connected. The numbering corresponds to the vessels that are listed in the table below.



Part	Connects to vessel
1	Waste vessel
2	Calibration fluid 1 vessel
3	Formulation fluid 1 vessel
4	Formulation fluid 2 vessel
5	Calibration fluid 2 vessel

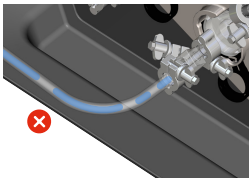
Part	Connects to vessel
6	Dilution fluid vessel
7	Product vessel

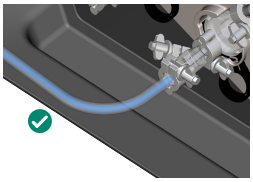
Connect vessels to the flow kit

Follow the steps below to connect the vessels to the flow kit after the flow kit is fully installed on the instrument.

Step	Action
1	Prime the input vessel lines all the way up to the shut-off valve or pinch clamp.

IMPORTANT
Make sure that there is no air trapped in the input vessel lines. Air in the input vessel lines negatively impacts the system performance.





2	Make sure that the shut-off valve or pinch clamp on each vessel line is closed. ***Note:*** *The software prompts the user to open or to close each input at the appropriate time during the run.*
3	Connect each vessel line to the flow kit as follows: **a.** Open the TC clamp on the flow kit lines and remove the cap covering the line. Make sure the gasket remains on the flow kit line when removing the cap. **b.** Store the cap in a safe location. **c.** Use the clamp provided with the flow kit to connect the vessel line to the flow kit TC connector. **d.** Repeat for each input and output vessel line.

6.4 Start and monitor a procedure

WARNING

Hazardous fluid leakage. Before a run, check that all tubing connections on the system are tight and secured in place so that the tubing remains connected during the run.

Refer to the system *User Manual* for information on performing a run and monitoring the formulation process. See *User documentation for Commercial Formulation System, on page 8*.

When a procedure is running, avoid touching the flow kit components. Significant manipulation of the kit can impact the results of the procedure or cause an alarm.

6.5 Procedures after a run

Introduction

This section describes how to prepare the flow kit for disposal and how to shut down the system after a run.

The flow kit must be disposed of in accordance with local regulations.

In this section

6.5.1 Uninstall the flow kit

Safety precautions

WARNING
Explosion hazard: Active connections. Do not connect or disconnect electrical cables to the flow meters outside the ***Install*** and ***Uninstall*** unit procedures. Connections must not be made or broken while there is power to the connection.

WARNING
Exposure to hazardous chemicals. If using hazardous chemicals, flush all the lines before removing the flow kit. If the lines are not flushed, the user can be exposed to hazardous chemicals when removing the flow kit.

WARNING
Flammable liquid spillage. Do not use the drip tray as a collection vessel. Collecting fluid in the drip tray can lead to spillage of hazardous or flammable chemicals.

Introduction

The uninstall unit procedure allows for an optional flush of the flow kit with calibration fluids before uninstalling. The uninstall unit procedure also enables an optional drain of the calibration flow meter. A user can skip either or both of these steps if a flush or drain is not required.

Note: *Skipping the flush step, drain step, or both might result in < 50 mL of reagents leaking out of the pump head and calibration flow meter during removal.*

Before you start the uninstall unit procedure with a flush or drain step, make sure:

- There is enough material in the calibration input vessels to provide the user-determined flush volumes for each line.
- There is sufficient space in the waste vessel to collect the user-determined flush volumes and the 388 mL of drained fluid from the flow kit.

The following sections describe how to disconnect the vessels, disconnect the calibration flow meter with and without running a drain procedure, and remove the flow kit from the instrument. The steps to uninstall the flow kit must be only performed when prompted by the software. Refer to the system *User Manual* for the detailed uninstall procedure, see *User documentation for Commercial Formulation System, on page 8*.

Disconnect a vessel

When prompted by the software, follow the steps below to disconnect a vessel.

Step	Action
1	For all lines: Close the shut-off valve or pinch clamp on the vessel line.
2	For waste and product output lines only: Close the pinch clamp on the flow kit line before disconnecting the vessel.
3	Open the TC clamp to disconnect the vessel line.
4	**Optional**. Replace the cap on the flow kit line and close the TC clamp. ***Note:*** *If the flow kit lines are not capped, fluid might leak out of the flow kit during the uninstallation.*

Run drain and disconnect flow kit from calibration flow meter

When prompted by the software to disconnect the flow kit from the calibration flow meter, the option to run a drain appears on the screen. Proceed to the following section if you do not want to run a drain. Follow the steps below to run a drain using the ***Run drain*** procedure and disconnect the calibration flow meter.

Step	Action
1	Open the pinch clamp on the waste line, and make sure there is a waste vessel connected to the flow kit.
2	Close the pinch valve on the calibration line above the calibration flow meter. 

Step	Action
3	Tap ***Run drain*** on the user interface. *Result:* The peristaltic pump moves fluid from the calibration loop to the waste line and into the waste vessel.
4	Open the TC connection above the calibration flow meter while the pump is running.  *Result:* Air is pulled into the calibration flow meter.
5	When air is visible in the calibration line below the calibration flow meter, close the pinch clamp below the calibration flow meter. 

Step	Action
6	Tap ***Stop drain***.
7	Open the TC clamp below the calibration flow meter. 
8	Optional. Replace the caps on the flow kit lines and close the TC clamps. ***Note:*** *If the flow kit lines are not capped, fluid might leak out of the flow kit during the uninstallation.*
9	Make sure all pinch clamps on the kit are closed before proceeding on the user interface. Refer to the system *User Manual* for detailed instructions, see *User documentation for Commercial Formulation System, on page 8*.

Disconnect flow kit from calibration flow meter without running a drain

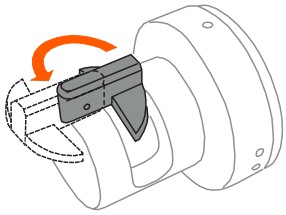
When prompted by the software to disconnect the flow kit from the calibration flow meter, the option to run a drain appears on the screen. If you do not want to run a drain, do not tap ***Run drain***. Follow the steps below to disconnect the calibration flow meter.

Step	Action
1	Close the pinch clamps on the calibration lines above and below the calibration flow meter. 
2	Open the TC clamps on the top and bottom of the calibration flow meter. 
3	Optional. Replace the caps on the flow kit lines and close the TC clamps. ***Note:*** *If the flow kit lines are not capped, fluid might leak out of the flow kit during the uninstallation.*
4	Make sure all pinch clamps on the kit are closed before proceeding on the user interface. Refer to the system *User Manual* for detailed instructions, see *User documentation for Commercial Formulation System, on page 8*.

Remove the flow kit

When prompted by the software to remove the flow kit, follow the steps below.

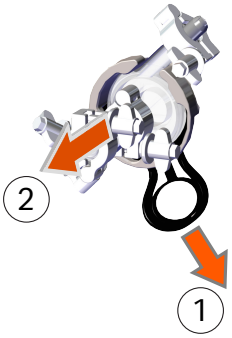
Step	Action
1	Open the safety locks on all seven pinch valves. Move the black lever on the pinch valves 180 degrees.



2 Remove the pump heads:

a. Pull and hold the pump head clip down and to the right (1).

b. Pull the pump head away from the instrument (2).



c. Release the pump head clip.

d. Repeat for each pump head.

3 Disconnect the flow meters:

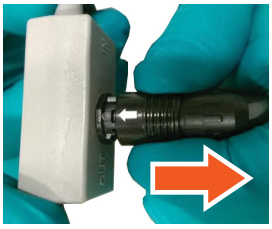
a. Unscrew the screw on the flow meter cover with a hex wrench.

b. Remove the flow meter cover and place it on the holder at the bottom right of the instrument.

c. Remove the flow meter from the housing.

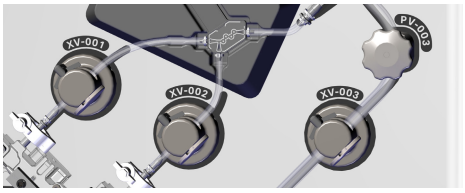
Step	Action

d. Pull back the latch and disconnect the cable from the flow meter, as shown in the image, to avoid damage to the cable. Reconnect the cable to the dummy connector.



e. Repeat for each flow meter.

4 Remove the tubing from **XV-001**, **XV-002**, **XV-003** and **PV-003**.

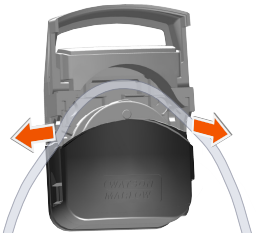


5 Remove the cartridge from the RFID module.

6 Remove the kit from **XV-101** and **XV-102**.

7 Open the peristaltic pump.

8 Remove the peristaltic pump tubing from the pump.



Step	Action
9	Remove the tubing from **XV-201** and **XV-202**. *Result:* The flow kit is now fully uninstalled.
10	Close all safety locks on the pinch valves. The valves will close at the end of the uninstall unit procedure.
11	Dispose of the flow kit in accordance with local regulations. ***Note:*** *When using NxGen commercial development flow kit, the flow kit can be stored between runs. Refer to the system User Manual for detailed instructions on running multiple batches with the same flow kit. See* *User documentation for Commercial Formulation System, on page 8**.*

Clean any spills and the instrument as described in *Section 7.5 Cleaning procedures, on page 130*.

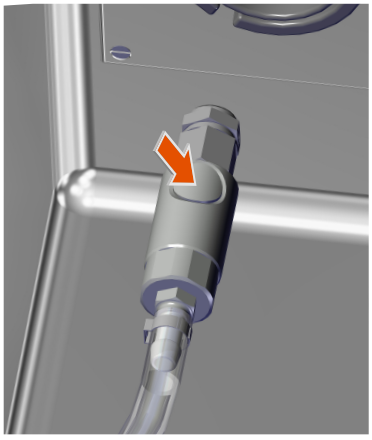
6.5.2 Shut down the system

CAUTION
Pinch risk. Make sure that all of the safety locks on the pinch valves are closed before shutting down the system. Valves close automatically when the power to the instrument is shut off.

Turn the power switch to the OFF position (**O**) to completely turn off power to the system.

6.5.3 Depressurize the system and disconnect air supply

After shutting down the system, follow these steps to depressurize the system, and optionally disconnect the air supply line.

Step	Action
1	Turn off the valve on the air supply line. ***Note:*** *The valve on the supply line is not a component of the system. Any shut-off valve must be supplied by the user.* *Result:* Air begins to slowly drain from the purge and pressurized enclosure.
2	Optional. Disconnect the air supply line as follows: **a.** Press the release button on the barbed connector firmly once.  *Result:* Air immediately vents through the compressed air port. The connection becomes loose, but the connector remains attached to the instrument. **b.** Press and hold the release button while pulling the connector completely away from the compressed air port.

7 Maintenance

About this chapter

This chapter provides information about maintenance that should be performed by users of the system.

To make sure that the system works according to specifications, planned maintenance must be performed annually by a Cytiva service engineer, or service personnel authorized by Cytiva. A list of planned maintenance actions is presented in this chapter.

In this chapter

7.1 Safety precautions

WARNING

All installation, maintenance, operation, and inspection must be carried out according to local regulations by adequately trained personnel.

WARNING

Explosion hazard. Maintenance or service of the product must not be performed in areas with a potentially explosive atmosphere.

WARNING

Explosion hazard. Before maintenance, or if the system is to be moved to a non-hazardous area (area not classified as potentially explosive atmosphere or hazardous location), make sure that any flammable solvents have been flushed out from the system.

WARNING

Electrical shock hazard. All installation, service and maintenance of components inside the electrical cabinet must be done by personnel authorized by Cytiva.

WARNING

Use only approved parts. Only spare parts and accessories that are approved or supplied by Cytiva can be used for maintaining or servicing the product.

WARNING

Decontaminate before maintenance or service. Before performing any maintenance or service work on the system, make sure that the system has been decontaminated.

7.2 Service and preventive maintenance

Introduction

Regular service and maintenance of Commercial Formulation System is necessary to maintain optimal condition and to extend the operational lifetime of the its 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.

Spare parts

Apart from the flow kits, the system has very few parts that a user may need to replace. Normally, parts are checked and, if necessary, replaced by service personnel during preventive maintenance.

7.3 User maintenance schedule

Introduction

The maintenance recommendations vary depending on how frequently you use your system. Note that the recommendation may not apply to your specific use of the system. The system owner is solely responsible for establishing applicable routines for periodic maintenance.

It is important that the user is always attentive about the status and operation of the equipment. The cause of any abnormal behavior or aberrant noise should be examined and removed. If the problem is non-trivial, contact your local Cytiva representative.

Maintenance in connection to each run or daily

The table below describes maintenance actions required for each run or daily, depending on which happens first.

Component	Action
Complete system	Clean the system according to the procedure described in *Section 7.5.1 General cleaning, on page 131*.
Peristaltic pump	After the flow kit has been uninstalled, follow the steps below: 1. Open the peristaltic pump **P-201**. 2. Clean the rollers of the pump as described in *Section 7.5.1 General cleaning, on page 131*. 3. Close the Peristaltic pump
Drip tray	Remove any fluid that is in the drip tray. Wipe the drip tray dry.
Calibration flow meter	Clean the calibration flow meter according to the instructions in *Section 7.5.2 Clean the calibration flow meter, on page 132*. Optionally, sanitize the calibration flow meter according to your internal SOP.

Maintenance annually or as needed

The table below lists maintenance actions that are required annually or as needed.

Component	Action
Complete system	A preventive maintenance procedure on all components, motors, sensors, pumps, and valves must be performed annually by trained and certified personnel. Contact your Cytiva representative.
Pneumatic valves	Open and close all pneumatic valves according to the instructions in *Section 8.3.2 Manual control of pneumatic valves, on page 162*, or using the ***Valve test*** described in *Section 8.4 Manual control of an operation, on page 168*. ***Note:*** *The user must have a sufficient access level to perform manual control of the system.* All valves should function as intended without causing any alarms or warnings.
System air vent filters	Replace system air vent filters once a year or earlier according to the service agreement.

Additional maintenance

The integrity of all ground connections must be periodically checked according to local regulations.

7.4 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.

7.5 Cleaning procedures

In this section

7.5.1 General cleaning

NOTICE

Only use chemicals that have been proven not to be harmful to the wetted parts of the product.

NOTICE

Kit damage. Do not use NaOH when cleaning the flow kit. The tubing walls can stick together where the tubing is squeezed, damaging the flow kit.

For proper function, the system must be kept clean and dry. Follow the recommendations below when cleaning the system. Always use a non-abrasive wipe to avoid altering the surface finish.

- Wipe the outer surfaces of the instrument with a non-abrasive wipe wetted with water to remove chemical stains and dust.
- Optionally, sanitize the outer surfaces by wiping them with one of the chemicals listed in *Allowed chemicals for external surfaces, on page 173*.
- If salt buffer is spilled on the valves, rinse carefully with water to remove salt crystals and wipe dry.
- Clean the system of infectious or aggressive fluids before service or maintenance. Make sure that the cleaning procedure flushes all possible flow paths in the system.
- To prevent corrosion, wipe the system dry after cleaning.

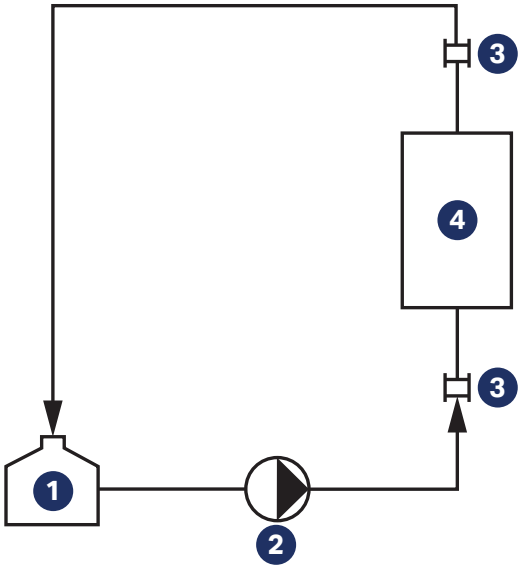
7.5.2 Clean the calibration flow meter

Introduction

To clean the calibration flow meter, it is recommended that the user sets up a cleaning-in-place (CIP) circulation loop. It is possible to flush the flow meter without removing it from the instrument by bringing a circulation pump and vessel close to the instrument. Alternatively, the flow meter can be removed from the instrument for cleaning, see instructions in the following sections.

CIP loop recommendations

Set up the CIP loop as shown in the figure below.



Part	Description
1	Reservoir
2	Pump
3	¾-inch TC connector
4	Calibration flow meter

Size the reservoir and tubing according to the following recommendations:

- Use tubing with an inner diameter of 0.5 inches.
- Add a sufficient volume of NaOH to the reservoir such that circulation through the loop is possible without drawing air bubbles into the loop.
- Make sure the calibration flow meter is subjected to a flow rate of at least 6.5 LPM during the CIP process.

Note: *An internal diameter of 3/8 inch can be used to calculate the flow velocity through the calibration flow meter.*

- It is recommended to run the CIP loop for at least 30 minutes.

The user is responsible for verifying the efficacy of the CIP process.

Remove the calibration flow meter

CAUTION

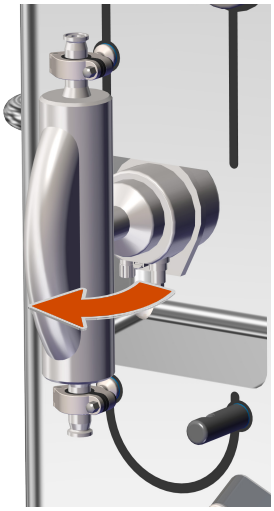
Heavy object. The calibration flow meter is heavy. Handle the unit with care to avoid personal injury.

Follow the steps below to remove the calibration flow meter for cleaning.

Step	Action
1	Disconnect the cable from the calibration flow meter.

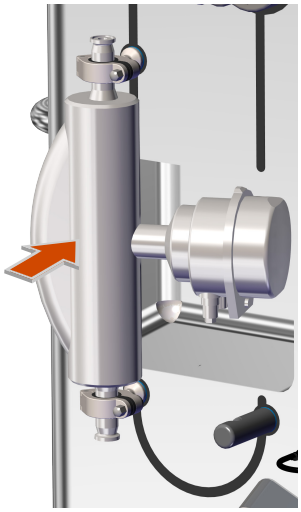
Step	Action
2	Loosen, but do not fully disconnect, the screws on the top and bottom hinges of the flow meter support using a wrench. It should be possible to rotate the flow meter while the screws are still connected.

3	Rotate the flow meter out of the recess of the instrument.



4	Use one hand to support the flow meter by pushing the flow meter against the instrument (perpendicular to the front panel of the instrument).

Note:
It is also possible to support the flow meter by gripping the T-connection of the flow meter.

Step	Action
	
5	Loosen the screws on the top and bottom hinges completely, until the hinges can open.
6	Lift the calibration flow meter out of the hinges, making sure to support the full weight of the flow meter.

7.5.3 Remove the pump head clips for cleaning

Follow the steps below to remove, clean, and replace the pump head clips.

Step	Action
1	Press and hold the release tab on the pump head clip.

2	Pull the loop of the clip down and to the right.

3	Clean the clip.
4	Slide the clip back into the pump head slot until you hear a click.

7.6 Replacing the battery

WARNING

The battery is not a user-replaceable item. Contact your local Cytiva representative or authorized distributor to arrange for a replacement battery to be fitted to the instrument.

Commercial Formulation System contains a built in lithium-ion coin cell battery to power the real-time clock and store time and date information if disconnected from the power supply.

Note: *A warning message appears on the user interface to indicate a low battery. See* *Section 8.2.3 Warning messages and corrective actions, on page 154**.*

7.7 Long-term storage

If the system is not used for a longer time period (more than a few days), perform the following actions:

1. Remove the flow kit (see *Section 6.5 Procedures after a run, on page 113*).
2. Clean the system (see *Section 7.5.1 General cleaning, on page 131*).
3. If the system is to be moved, switch off the system power and air supply.
4. Store the instrument in accordance with the requirements in *Environmental requirements, on page 59*.

NOTICE

Kit damage. Do not leave a flow kit mounted on the system for an excessively long time. The tubing walls might stick together where the tubing is squeezed, which can cause high pressure alarms when running the system.

NOTICE

Kit damage. Do not use NaOH when cleaning the flow kit. The tubing walls can stick together where the tubing is squeezed, damaging the flow kit.

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.

In this chapter

8.1 General troubleshooting

The following table lists problems, their possible causes, and corrective actions. The following problems do not result in on-screen alarm or warning messages.

Problem	Possible cause	Corrective action
Power failure during a run	The system does not have power.	Check that the power to the system is available. Restart as described in *Restart after power failure or emergency shutdown, on page 20*. If the power supply is reaching the system and the system is not turning on, contact a Cytiva representative.
Cavitation (air bubbles in the flow path)	The liquid source is restricted.	Make sure there are no restrictions in the upstream lines, such as closed input lines. Re-prime any individual line using the ***Prime line*** tool. See *Section 8.4 Manual control of an operation, on page 168*.
Incorrect flow reading	Flow meter cables are not connected correctly.	Make sure that the flow meter is connected as in *Connect the flow meter cables, on page 105*.
	Priming was not done correctly: bubbles remain or there is a taring problem	Remove air bubbles by re-running the priming step or using the manual priming tool to re-prime all lines. Refer to the system *User Manual* for detailed instructions, see *User documentation for Commercial Formulation System, on page 8*.
	Fluid viscosity does not match the viscosity set in the batch recipe.	• Make sure the correct fluid is being used, it should match the fluid expected by the recipe. • Make sure the correct recipe is being used.
	Calibration was not done correctly.	• Re-run the calibration step. • Make sure the input and waste output vessels and lines are not disturbed during the calibration. • Make sure no manual controls are active while the calibration is running. See *Section 8.3.2 Manual control of pneumatic valves, on page 162*.
Air leakage	Air leakage from the compressed air supply or supply line.	If the air leakage sound is audible from inside the system, contact a Cytiva representative.

8.2 Alarms and warnings

In this section

8.2.1 Overview

There are two ways the user interface notifies the user of a problem:

- **Alarm**: Alarms are used to stop or pause the current operation if process parameters or system conditions exceed preset high or low limits, or meet other criteria. Alarms require acknowledgement and the user to perform a corrective action in order to continue existing unit procedures or start new procedures.
- **Warning**: Warnings are shown to warn users that process parameters or system conditions have exceeded preset high or low limits, or met other warning criteria. Warnings do not require acknowledgment and do not stop the active operation.

The following table gives a description of the interruption and corrective actions possible for each type of notification.

Type	Description	Corrective action
Alarm during a formulate unit procedure	• The formulate unit procedure is set to the ***Pause*** state. • Valves go to their default state (closed) and all pumps stop. • A red bar is shown on the user interface and the red status indicator light is illuminated. • If the alarm occurred while the formulation was mixing to the product outlet, the alarm is logged in the batch record. • The alarm message is added to the event log.	• Users can navigate between the screens on the user interface to help identify the condition that caused the alarm, and to perform troubleshooting actions described in the following sections. • Once the alarm condition has been rectified, the alarm can be reset by acknowledging the alarm message. • The formulate unit procedure can be restarted. See *Acknowledge an alarm, on page 144* for more information on acknowledging an alarm and restarting the unit procedure.

Type	Description	Corrective action
Alarm during an install, prime, calibrate, or uninstall unit procedure	• The active operation of the unit procedure is stopped. • Valves go to their default state (closed) and all pumps stop. • A red bar is shown on the user interface and the red status indicator light is illuminated. • The alarm message is added to the event log.	• Users can navigate between the screens on the user interface to help identify the condition that caused the alarm, and to perform troubleshooting actions described in the following sections. • Once the alarm condition has been rectified, the alarm can be reset by acknowledging the alarm message. • Depending on the unit procedure when the alarm occurred, the operation can usually be restarted from the screen of the active unit procedure. See *Acknowledge an alarm, on page 144* for more information on acknowledging an alarm and restarting the unit procedure.
Alarm with no active unit procedure	• Valves go to their default state (closed) and all pumps stop. • A red bar is shown on the user interface and the red status indicator light is illuminated. • The alarm message is added to the event log.	• Users can navigate between the screens on the user interface to help identify the condition that caused the alarm, and to perform troubleshooting actions described in the following sections. • Once the alarm condition has been rectified, the alarm can be reset by acknowledging the alarm message. See *Acknowledge an alarm, on page 144* for more information on acknowledging an alarm.

Type	Description	Corrective action
Warning	• A yellow bar is shown on the user interface and the yellow status indicator light is illuminated while the warning is active. • The active unit procedure continues to run, and new unit procedures can be started. • If the warning is defined in the recipe for the batch and occurs while the formulation is mixing to the product outlet, the warning is logged in the batch record. • The warning message is added to the event log.	Users can navigate between the screens on the user interface to help identify the condition that caused the warning, and to perform troubleshooting actions.

Alarm and warning status

The status column can have up to three letters:

- ***I***: incoming, alarm triggered
- ***O***: outgoing, alarm triggered
- ***A***: acknowledged, alarm has been acknowledged with the ***Acknowledge*** button

An alarm will first show the status ***I*** when it is triggered, then ***IO*** when the alarm condition goes away, and then ***IOA*** when the alarm has been acknowledged. The ***IOA*** status is displayed with a white background.

Warnings do not need to be acknowledged. Warnings can either show the status ***I*** or ***IO***.

Acknowledge an alarm

Follow the steps below to acknowledge an alarm

Step	Action
1	Do one of the following to access the ***Alarms*** screen: • Tap ***View alarms*** on the red status bar that appear at the top of the screen, or

Step	Action
	• Tap ***Alarms*** button at the bottom of the screen.
2	In the ***Active*** tab, tap ***Acknowledge alarms***. *Result:* All active alarms are acknowledged. The status of an alarm is displayed as ***A*** to indicate that it has been acknowledged.
3	If the alarm occurs during a unit procedure, tap ***Resume*** to return to the unit procedure screen.

8.2.2 Alarm messages and corrective actions

The following table lists the alarm messages that can appear on the user interface, common causes, and corrective actions.

Note: *Not all users have access to the manual controls for troubleshooting. See Permissions for each user role, on page 42 for details about user access.*

Message	Description	Corrective action
`Emergency stop is pressed`	The **Emergency Stop** button has been pressed.	Correct the condition that caused the emergency stop. Reset the **Emergency Stop** button by turning clockwise.
`Air purge not ready`	Insufficient air supply caused by, for instance, malfunctioning air supply equipment or a leaking air hose.	Make sure the air supply pressure is within required range, and that the air supply can provide the flow rate required. See *Compressed air specifications, on page 171*.
`Air supply pressure high`	The pressure in the air supply line is too high.	Contact a Cytiva representative.
`Air supply pressure low`	The pressure in the air supply line is too low.	• Make sure air is being supplied to the system. • Increase the air supply pressure.
`PLC-HMI communication watchdog timed out`	There is an error in the communications between the internal systems, or the user has intentionally exited the HMI runtime from the ***Admin / System*** screen.	• Make sure any modifications to the system IP addresses have correctly followed the setup procedures. See *Network settings, on page 68*. • If the issue is not resolved, shut down the system and then restart the system.

Message	Description	Corrective action

`Valve 001 (XV-001) not in commanded state`
`Valve 002 (XV-002) not in commanded state`
`Valve 002 (XV-003) not in commanded state`
`Valve 101 (XV-101) not in commanded state`
`Valve 102 (XV-102) not in commanded state`
`Valve 201 (XV-201) not in commanded state`
`Valve 202 (XV-202) not in commanded state`
	The valve named is open when it is expected to be closed, or closed when it is expected to be open.	• Make sure all safety locks on the pinch valves are closed. To close a safety lock:
		1. Open the valve manually as described in *Section 8.3.2 Manual control of pneumatic valves, on page 162*.
		Note:
		When opening the valves, all parts of the flow kit can be filled with liquid, including inlets and outlets that are not in use. To avoid spillage of liquid, do not remove the end caps from connections that are not used.
		2. Turn the black lever on the pinch valve 180 degrees to close the safety lock.
		3. Close the valve manually.
		4. Optional. Test that all valves are behaving as expected by running a ***Valve test***. See *Section 8.4 Manual control of an operation, on page 168*.

	The flow kit tubing is not installed correctly.	• Make sure nothing is inserted in the valve besides the correct section of flow kit tubing. • Adjust the tubing by opening and closing the valves as described in *Section 8.3.2 Manual control of pneumatic valves, on page 162*. ***Note:*** *When opening the valves, all parts of the flow kit can be filled with liquid, including inlets and outlets that are not in use. To avoid spillage of liquid, do not remove the end caps from connections that are not used.*

Message	Description	Corrective action
	If the alarm is accompanied by `No air supply to the system`, the alarm is caused by a compressed air failure.	Make sure the air supply pressure is within required range.
	There is a position sensor failure.	Check if the valve can be opened or closed manually as in *Section 8.3.2 Manual control of pneumatic valves, on page 162*. If the alarm persists, contact a Cytiva representative.

`Pump 1 (P-001) speed while running is low`
`Pump 2 (P-002) speed while running is low`
`Pump 3 (P-003) speed while running is low`
	There is possible forward-flow.	• Make sure the inlet and outlet vessel heights are within the recommended ranges.
		• Make sure no additional pressure is being applied to inlet vessel fluids.
		• Make sure the pump is not in manual mode with a speed setpoint below 2 RPM.
		• Make sure the flow meter sensors are connected to the correct flow meter cables.

Message	Description	Corrective action

`Pump 1 (P-001) speed while running is high`
`Pump 2 (P-002) speed while running is high`
`Pump 3 (P-003) speed while running is high`
	There is a possible blocked line.	• Make sure the pinch clamps are open so there is a direct path to the collection vessel.
		• Make sure that no valves along the line from the pump to the collection vessel have been manually closed, blocking flow. See *Section 8.3.2 Manual control of pneumatic valves, on page 162*.
		• Material might be building up in one of the components downstream of the pumps. Contact a Cytiva representative.
		• Make sure the inlet and outlet vessel heights are within recommended ranges and are open. See *Vessel placement at ≤ 600 m elevation, on page 93*.
		• Make sure the pump is not in manual mode with a speed setpoint above 8800 RPM. See*Section 8.3.4 Manual control of pumps, on page 165*.
		• Make sure the flow meter sensors are connected to the correct flow meter cables.

`Error from flow meter 1 (FE-001)`
`Error from flow meter 2 (FE-002)`
`Error from flow meter 3 (FE-003)`
	The named flow meter is experiencing an error. Check the flow meter dialog on the ***Process*** screen for detailed status information.	• Make sure the flow meter sensor is connected to the flow meter cable.
		• Make sure the flow meter sensor does not contain any gas bubbles. Prime the system again if necessary.
		• Make sure the flow meter sensor contains a homogeneous fluid.
		• Make sure the flow meter sensor viscosity setting matches the current fluid.

Message	Description	Corrective action

`Flow meter 1 (FE-001) flow is zero or negative while pump is running`
`Flow meter 2 (FE-002) flow is zero or negative while pump is running`
`Flow meter 3 (FE-003) flow is zero or negative while pump is running`
	There is a possible blocked line.	• Make sure the pinch clamps are open so there is a direct path to the collection vessel.
		• Make sure inlet and outlet vessel heights are within the recommended ranges and the lines are open.
		• Make sure the flow meter sensors are connected to the correct flow meter cables.
		• Make sure that no valves along the line from the pump to the collection vessel have been manually closed, blocking flow. See *Section 8.3.2 Manual control of pneumatic valves, on page 162*.

`Mixer total flow rate is below low alarm level during formulation`	The mixer total flow rate is below the low alarm level during formulation.	• Check the alarm levels set in the recipe. • Make sure that fluid is available on all input lines. • Make sure the output vessel has enough capacity to hold the output product.
`Mixer ratio is below low alarm level during formulation`	The mixer ratio is below the low alarm level during formulation.	
`Dilution ratio is below low alarm level during formulation`	The dilution ratio is below the low alarm level during formulation.	
`Mixer total flow rate is above high alarm level during formulation`	The mixer total flow rate is above the high alarm level during formulation.	
`Mixer ratio is above high alarm level during formulation`	The mixer ratio is above the high alarm level during formulation.	
`Dilution ratio is above high alarm level during formulation`	The dilution ratio is above the high alarm level during formulation.	

Message	Description	Corrective action
`RFID tag not found while flow kit is installed`	The RFID tag is not detected by the RFID module while the flow kit is installed.	Make sure the flow kit cartridge is correctly installed on the system. See *Install flow kit components, on page 100*.
`PLC clock time is invalid: set to before 2022`	The date is set to before 2022.	Make sure the correct date and time are set. See *Section 5.2.1 Change date and time, on page 78*.

`Pump 1 (P-001) status message has an active error, see pump faceplate for details`
`Pump 2 (P-002) status message has an active error, see pump faceplate for details`
`Pump 3 (P-003) status message has an active error, see pump faceplate for details`
	The named pump is experiencing an error. Check the pump dialog on the ***Process*** screen for detailed status information.	• Make sure the pump head is installed correctly on the front of the instrument. See *Install flow kit components, on page 100*.
		• Make sure the ambient temperature is within the required limits. See *Environmental requirements, on page 171*.
		• Make sure the fluid temperature is 5°C to 45°C
		• Make sure there is no damage to the pump head on the flow kit.

`Pump 1 (P-001) modbus communications error`
`Pump 2 (P-002) modbus communications error`
`Pump 3 (P-003) modbus communications error`
	The pump named is experiencing a problem with communications.	Shut down the system, including powering off. Then restart the system.

`Flow meter 1 (FE-001) modbus communications error`
`Flow meter 2 (FE-002) modbus communications error`
`Flow meter 3 (FE-003) modbus communications error`
	The flow meter named is experiencing a problem with communications.	• Make sure the flow kit is fully installed. See *Section 6.3.2 Install flow kit, on page 99*.
		• Make sure there is no alarm that is related to the air purging system.
		• Shut down the system, including powering off. Then restart the system.

`Calibration meter modbus communications error`	The calibration flow meter is experiencing a problem with communications.	• Make sure the calibration flow meter cable is connected. • Shut down the system. Then restart the system.

Message	Description	Corrective action

`Flow meter 1 flow is nonzero while valve 001 (XV-001) is closed`
`Flow meter 2 flow is nonzero while valve 002 (XV-002) is closed`
`Flow meter 3 flow is nonzero while valve 003 (XV-003) is closed`
	The flow meter is measuring a non-zero value for the flow rate while the valve on the same line is closed.	• Make sure the flow kit is fully installed. See *Section 6.3.2 Install flow kit, on page 99*.
		• Make sure the line is fully primed (no bubbles). If there are bubble, re-prime the line using the ***Prime line*** tool. See *Section 8.4 Manual control of an operation, on page 168*.
		• Make sure there is no alarm that is related to the air purging system.
		• Make sure flow along the line is stopped (valves closed) and then update the calibration offset of the affected flow meter. See *Section 8.3.5 Manual control of flow meters, on page 166*.

`Upstream external system for input line 1 is not ready`
`Upstream external system for input line 2 is not ready`
`Upstream external system for dilution line is not ready`
	The upstream system connected to the line identified is not ready and the input line cannot be used.	• Check that the correct handshake settings are enabled in the ***Admin / Network settings*** screen.
		• Confirm connection and configuration of the external OPC UA client and servers.

`Downstream external system for output waste line is not ready`	The downstream external system connected to the output waste line is not ready.	
`Downstream external system for output product line is not ready`	The downstream external system connected to the output product line is not ready.	
`System stop triggered by external system`	A system stop has been triggered by an external system.	

Message	Description	Corrective action

`Pump 1 (P-001) speed while disabled is high`
`Pump 2 (P-002) speed while disabled is high`
`Pump 3 (P-003) speed while disabled is high`
	The named pump has a high speed while the target state is disabled.	Make sure the pump head is installed correctly on the front of the instrument. See *Install flow kit components, on page 100*.

8.2.3 Warning messages and corrective actions

The following table lists the warning messages that can appear on the user interface, common causes, and corrective actions.

Note: *Not all users have access to the manual controls for troubleshooting. See Permissions for each user role, on page 42 for details about user access.*

Message	Description	Corrective action
`Flow meters have not completed their warmup timer`	The flow meters have not completed the required warm up and the flow sensing accuracy might be compromised.	Wait for flow meters to complete their warmup.

`Pump 1 (P-001) device settings do not match expected values`
`Pump 2 (P-002) device settings do not match expected values`
`Pump 3 (P-003) device settings do not match expected values`
	The current settings for the pump named do not match the values expected by the software.	No corrective action available. If the warning persists, contact a Cytiva representative.

`Calibration flow meter device settings do not match expected values`	The current settings for the calibration flow meter do not match the values expected by the software.	

`Flow meter 1 (FE-001) device settings do not match expected values`
`Flow meter 2 (FE-002) device settings do not match expected values`
`Flow meter 3 (FE-003) device settings do not match expected values`
	The current settings for the flow meter named do not match the expected values.	

`Real-time clock backup battery voltage is low`	The voltage of the clock backup battery is low.	
`Flow kit has exceeded the maximum allowed install time`	The flow kit installed on the system has been installed for longer than the allowed time, based on the type of flow kit.	Install a new flow kit.

Message	Description	Corrective action
`Flow kit has exceeded the maximum allowed cumulative install time`		

`Pump 1 (P-001) speed while running is high`
`Pump 2 (P-002) speed while running is high`
`Pump 3 (P-003) speed while running is high`
	There is a possible blocked line on the line identified.	• Make sure the pinch clamps are open so there is a direct path to the collection vessel.
		• Make sure that no valves along the line from the pump to the collection vessel have been manually closed, blocking flow. See *Section 8.3.2 Manual control of pneumatic valves, on page 162*.
		• Material might be building up in one of the components down-stream of the pumps. Contact a Cytiva representative.
		• Make sure the inlet and outlet vessel heights are within recom-mended ranges and are open. See *Vessel placement at ≤ 600 m elevation, on page 93*.
		• Make sure the pump is not in manual mode with a speed setpoint above 8800 RPM. See*Section 8.3.4 Manual control of pumps, on page 165*.
		• Make sure the flow meter sensors are connected to the correct flow meter cables.

`Pump 1 (P-001) status message has an active warning, see pump faceplate for details`
`Pump 2 (P-002) status message has an active warning, see pump faceplate for details`
`Pump 3 (P-003) status message has an active warning, see pump faceplate for details`
	The named pump is experiencing an error. Check the pump dialog on the ***Process*** screen for detailed status information.	• Make sure the pump head is installed correctly on the front of the instrument. See *Install flow kit components, on page 100*.
		• Make sure the ambient tempera-ture is within the required limits. See *Environmental requirements, on page 171*.
		• Make sure the fluid temperature is 5°C to 45°C
		• Make sure there is no damage to the pump head on the flow kit.

Message	Description	Corrective action
Calibration flow meter modbus communications error	The calibration flow meter is experiencing a problem with communications.	• Make sure the calibration flow meter cable is connected. • Shut down the system. Then restart the system.
The available memory for the audit trail log and other records is low, free up space as soon as possible	The available memory for the audit trail log and other records is low and future data might not be possible to save	• Archive some logs, unused recipes, or batch records. • Transfer exported and archived records off of the built-in Exports folder to external storage. Refer to the system *User Manual* for more information, see *User documentation for Commercial Formulation System, on page 8*.
Air supply pressure high	The air supply pressure is high.	Contact a Cytiva representative.
Air supply pressure low	The air supply pressure is low.	• Make sure air is being supplied to the system. • Increase the air supply pressure.
Air purge error active	There is a problem with the air supply such as malfunctioning air supply equipment or a leaking air hose.	Make sure the air supply pressure is within required range, and that the air supply can provide the flow rate required. See *Compressed air specifications, on page 171*.
Flow meter cable connections have not been confirmed while a flow kit is installed, see process page for details	The connections to the flow meter cables have not been confirmed as connected by the user, though a flow kit is installed on the instrument.	• Navigate to the ***Process*** screen and tap ***Confirm*** to confirm the flow meter sensor cables are all connected. • Uninstall the flow kit using the ***Uninstall*** unit procedure. Refer to the system *User Manual* for details, see *User documentation for Commercial Formulation System, on page 8*.
Mixer total flow rate is below low warning level during formulation	The mixer total flow rate is below the low warning level during the formulation unit procedure.	• Check the alarm levels set in the recipe. • Make sure that fluid is available on all input lines.

Message	Description	Corrective action
Mixer ratio is below low warning level during formulation	The mixer ratio is below the low warning level during the formulation unit procedure.	• Make sure the output vessel has enough capacity to hold the output product.
Dilution ratio is below low warning level during formulation	The dilution ratio is below the low warning level during the formulation unit procedure.	
Mixer total flow rate is above high warning level during formulation	The mixer total flow rate is above the high warning level during the formulation unit procedure.	
Mixer ratio is above high warning level during formulation	The mixer ratio is above the high warning level during the formulation unit procedure.	
Dilution ratio is above high warning level during formulation	The dilution ratio is above the high warning level during the formulation unit procedure.	
Line 1 is empty during formulation	Line 1 is empty during the formulation unit procedure.	Make sure that fluid is available on the identified input line.
Line 2 is empty during formulation	Line 2 is empty during the formulation unit procedure.	
Dilution line is empty during formulation	The dilution line is empty during the formulation unit procedure.	

Message	Description	Corrective action

`Valve 001 (XV-001) not in commanded state`
`Valve 002 (XV-002) not in commanded state`
`Valve 002 (XV-003) not in commanded state`
`Valve 101 (XV-101) not in commanded state`
`Valve 102 (XV-102) not in commanded state`
`Valve 201 (XV-201) not in commanded state`
`Valve 202 (XV-202) not in commanded state`
	The valve named is open when it is expected to be closed, or closed when it is expected to be open.	• Make sure all safety locks on the pinch valves are closed. To close a safety lock:
		1. Open the valve manually as described in *Section 8.3.2 Manual control of pneumatic valves, on page 162*.
		Note:
		When opening the valves, all parts of the flow kit can be filled with liquid, including inlets and outlets that are not in use. To avoid spillage of liquid, do not remove the end caps from connections that are not used.
		2. Turn the black lever on the pinch valve 180 degrees to close the safety lock.
		3. Close the valve manually.
		4. Optional. Test that all valves are behaving as expected by running a ***Valve test***. See *Section 8.4 Manual control of an operation, on page 168*.

	The flow kit tubing is not installed correctly.	• Make sure nothing is inserted in the valve besides the correct section of flow kit tubing. • Adjust the tubing by opening and closing the valves as described in *Section 8.3.2 Manual control of pneumatic valves, on page 162*. ***Note:*** *When opening the valves, all parts of the flow kit can be filled with liquid, including inlets and outlets that are not in use. To avoid spillage of liquid, do not remove the end caps from connections that are not used.*

Message	Description	Corrective action
	There is a problem with the compressed air supply pressure	Make sure the air supply pressure is within required range.

8.3 Manual control of individual components

In this section

8.3.1 Introduction

Manual control of each component can be activated on the user interface in order to perform troubleshooting actions. When one of the components is in manual control mode, the status bar shows the message ***Manual control active*** on the upper left side of the user interface.

The user must have a sufficient access level to perform manual control of the system. See *Permissions for each user role, on page 42*.

The table below gives the manual actions available for each of the components.

Component	Description
Pneumatic valves	Manually adjust the valve state (open or closed)
Peristaltic pumps	Manually run or stop the peristaltic pump
Pumps	Manually run or stop the pump ***Note:*** *The pump can be controlled to either a flow setpoint or a fixed speed.*
Flow meters	• Manually set the fluid viscosity expected by the flow meter (occurs automatically during ***Prime*** and ***Formulate***) • Run the automatic zero adjustment and update the calibration offset ***Prime***)
Calibration flow meter	Manually reset the value for the totalizer volume of the calibration flow meter

8.3.2 Manual control of pneumatic valves

Introduction

WARNING

Never put fingers or any objects other than the intended tubing into the pinch valve opening.

CAUTION

Pinch hazard. Be careful to avoid squeezing or crushing injuries when installing tubing in pinch valves.

There are two ways to manually open and close the pneumatic valves on the system:

- **Option 1**: Open individual valves from the ***Process*** screen.
- **Option 2**: Open multiple valves simultaneously from the ***Valves*** screen

Open individual valves from the *Process* screen

Follow the steps below to open individual valves from the ***Process*** screen.

Step	Action
1	Tap ***Controls*** →***Process***.
2	Tap the valve symbol of the valve to be opened. The example below shows the icon for valve **XV-202**.  *Result:* A dialog box with valve information appears on the screen.
3	Tap ***Manual*** to switch into manual control mode.
4	Tap either: • ***Open*** to open the valve • ***Closed*** to close the valve

Step	Action
	Result: The valve immediately moves to the chosen position.
5	Tap the X in the top right corner of the dialog box. *Result:* The user interface returns to the ***Process*** screen. Valves under manual control are shown with a blue border and a hand symbol. 
6	To return to automatic control mode, open the valve dialog box again and tap ***Auto***, then close the dialog.

Open multiple valves from the *Valves* screen

Follow the steps below to open multiple valves simultaneously from the ***Valves*** screen.

Step	Action
1	Tap ***Controls*** →***Valves***.
2	Tap the check box next to the valve icon for the valve or valves to be opened. ***Tip:*** *Tap* ***Select all*** *to select all check boxes. Tap* ***Deselect all*** *to deselect all check boxes.*
3	Tap ***Manual*** to switch into manual control mode.
4	Tap either: • ***Open*** to open the selected valve or valves • ***Closed*** to close the valve or valves
5	Tap ***Apply settings***. *Result:* The valve or valves chosen move to the chosen positions.
6	To return to automatic control mode for the selected valves, tap ***Auto***, then ***Apply settings***.

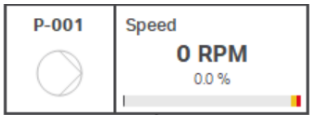
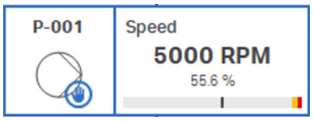
8.3.3 Manual control of peristaltic pump

Follow the steps below to manually control the peristaltic pump.

Step	Action
1	Tap ***Controls*** →***Process***.
2	Tap the peristaltic pump symbol.  *Result:* A dialog box with the peristaltic pump information appears on the screen.
3	Tap ***Manual*** to switch into manual control mode.
4	Tap ***Start pump***. *Result:* The status bar appears green and shows manual control is active.
5	Tap the cross on the top right corner of the dialog box, or tap ***Return to process*** on the top right corner of the screen. *Result:* The user interface returns to the ***Process*** screen. The peristaltic pump under manual control is shown with a blue border and a hand symbol. 
6	To return to automatic control mode, open the peristaltic pump dialog box again and tap ***Auto***, then close the dialog box.

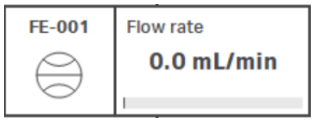
8.3.4 Manual control of pumps

Follow the steps below to manually control the pumps.

Step	Action
1	Tap ***Controls*** →***Process*** →***Overview***.
2	Tap the pump symbol. The example below shows the icon for pump **P-001**.  *Result:* A dialog box with the pump information appears on the screen.
3	Tap ***Manual*** to switch into manual control mode.
4	Do one of the following: • Tap ***Flow*** and enter the applicable value. • Tap ***Speed*** and enter the applicable value.
5	Tap ***Start pump***. *Result:* The status bar appears green and shows manual control is active.
6	Tap the X on the top right corner of the dialog box, or tap ***Return to process*** on the top right corner of the screen. *Result:* The user interface returns to the ***Process*** screen. Pumps under manual control are shown with a blue border and a hand symbol. 
7	To return to automatic control mode, open the pump dialog box and tap ***Auto***, then close the dialog box.

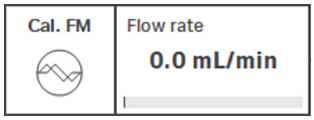
8.3.5 Manual control of flow meters

Follow the steps below to manually control the flow meters.

Step	Action
1	Tap ***Controls*** →***Process*** →***Overview***.
2	Tap the flow meter symbol. The example below shows the icon for flow meter **FE-001**.  *Result:* A dialog box with the flow meter information appears on the screen.
3	Perform manual operations as needed: **a.** Change the fluid viscosity expected by the flow meter: Enter the applicable value and then tap ***Set viscosity***. Wait for the operation to complete. *Result:* The value of ***Viscosity*** (left) is updated to match the set value (right). **b.** Update the calibration offset: While flow is stopped, tap ***Set zero***. Wait for the operation to complete. *Result:* The flow meter will perform a zero adjustment and the value of ***Calibration offset*** is updated.
4	Tap the X in the top right corner of the dialog box. *Result:* The user interface returns to the ***Process*** screen.

8.3.6 Manual reset of the calibration flow meter

Follow the steps below to manually reset the calibration flow meter.

Step	Action
1	Tap ***Controls*** →***Process***.
2	Tap the calibration flow meter symbol.  *Result:* A dialog box with the calibration flow meter information appears on the screen.
3	Tap ***Reset*** to reset the ***Totalizer volume***. Wait briefly for the operation to complete. *Result:* The ***Totalizer volume*** is changed to 0.0 L.
4	Tap the X in the top right corner of the dialog box. *Result:* The user interface returns to the ***Process*** screen.

8.4 Manual control of an operation

Overview

Tools are pre-defined actions that the user can use to manually control an operation outside of the automated unit procedure.

Tool	Description
Prime line	Runs the peristaltic pump at a fixed speed and pulses valves on a single selected line. This tool is used to flush air bubbles if they are introduced into a line after the system has been primed.
Fill line	Runs all active line pumps at a fixed flow rate. This tool is used to fill up the lines after the mixer, or fill an outlet line connected to the waste output.
Flush line	Runs the peristaltic pump at a fixed speed and runs a single line pump at a fixed speed. This tool is used to drain an input vessel to the waste output, or flush a specific fluid through the system. The manual flush can be set to flush a specific volume of fluid.
Valve test	Runs the same valve test operation that is used in the install unit procedure. The tool is used if the user needs to troubleshoot an issue with valve opening or closing. ***Note:*** *Only use **Valve test** when there is no fluid in the lines.*

9 Reference information

About this chapter

This chapter lists the technical specifications of Commercial Formulation System. 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
Power consumption, operation	250 VA (typical) max. 690 VA
Power consumption, idle	90 VA
Transient overvoltages	Overvoltage category II
Power outlet type	Grounded mains outlets
Number of power outlets	• 1 outlet for the instrument • 1 outlet for the Ethernet box, if applicable
Location of power sockets	Maximum 2 m from the system[1]
Dimensions (W × D × H)	120 x 80 x 170 cm
Weight	270 kg
Control system	Integrated 19" HMI panel, Ethernet port
Acoustic noise level	Normal operation: 51 dB Maximum: 61 dB
Enclosure protective class	IP 54
Battery	Clock battery located in the PLC module (Li-ion coin cell).
Explosive atmosphere classification	See *Explosive atmosphere and hazardous location classifications, on page 186*

[1] Only applies when the instrument is NOT used in an explosive atmosphere.

Environmental requirements

Parameter	Requirement
Allowed location	Indoor use only
Ambient temperature, operation	15°C to 25°C ***Note:*** *The explosive atmosphere classifications are valid for operation between 10°C to 30°C.*
Ambient temperature, storage	10°C to 30°C
Ambient temperature, transportation	-25°C to 60°C
Relative humidity	25% to 65%, non-condensing
Altitude, operation	Up to 2000 m ***Note:*** *Guidance for vessel placement differs for users operating the system above 600 m.*
Pollution degree of the intended environment	Pollution degree 2

Compressed air specifications

The table below shows the requirements for the compressed air supply system.

Parameter	Specification
Compressed air pressure	6.0 to 8.0 bar g
Compressed air supply tubing	Pneumatic tubing with 13 mm inner diameter rated to operate at 8 bar g minimum
Compressed air supply connection	Female barbed connector for 13 mm tubing
Compressed air flow rate, purge[1]	390 SL/min
Compressed air flow rate, operation	6 to 8 SL/min
Air quality	Oil and particle free[2] (ISO 8571-1:2010 Class 3.4.4)

[1] The supply must be able to provide this flow rate for 60 seconds when the system powers up.
[2] Use a 5 µm filter to filter particles.

Calibration flow meter specifications

Parameter	Specification
Type	Coriolis mass flow meter
Weight	8.2 kg (18 lbs)
Max measurement error	Mass flow (liquid): ±1% (standard)
Wetted materials	Measuring tube: 1.4539 (904L); 1.4404 (316/316L); Alloy C22, 2.4602 (UNS N06022) Connection: 1.4404 (316/316L); Alloy C22, 2.4602 (UNS N06022); 1.4301 (F304)
Housing material	Standard: 1.4301 (304)

9.2 Chemical resistance

Allowed chemicals for external surfaces

The following chemicals can be used to clean the external surfaces of the system:

Chemical	Concentration
Isopropyl alcohol	70%
Hydrogen peroxide	3%
Sodium hypochlorite	2%
Acetic acid	10%

Allowed chemicals for wetted surfaces

You must consider the compatibility of the wetted parts and your process chemicals so that no negative interaction takes place. Also make sure that your process chemicals do not damage the system components, compromising the safety of the system.

NOTICE

Only use chemicals that have been proven not to be harmful to the wetted parts of the product.

Contact your local Cytiva representative if you are not sure of the compatibility of your chemicals.

The following chemicals have been validated for use with the system:

- 100% Ethanol
- Phosphate buffered saline
- Citrate buffer
- Acetate buffer

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.

Disposal of batteries

Waste batteries and accumulators must not be disposed of as unsorted municipal waste and must be collected separately. Follow applicable local regulations for recycling of batteries and accumulators.

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 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.

9.4.4 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 Commercial Formulation System 1002276	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.

9.4.5 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.

9.4.6 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.

9.4.7 Other regulations and standards

Introduction

This section describes the additional standards that apply to the product.

Japan

The equipment is designated as a Specification of Type by the Ministry of Internal Affairs and Communications: The RFID module used in the NanoAssemblr Commercial Formulation System is designated as a Specification of Type by MIC.

Specification of Type name: Inductive read/write communication equipment

Manufacturer Name: SIEMENS K.K

Model Name for RFID: RF-340R

Specification Number: 第 AC-19061 号

当該装置は、総務省の型式指定を受けたものです：NanoAssemblr Commercial Formulation System に使用されている RFID モジュールは、総務省の仕様書に指定されています。

仕様書名：インダクティブ方式読み書き通信装置

製造元名： SIEMENS K.K

RFID 用型名： RF-340R

仕様番号： 第 AC-19061 号

South Africa

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.

9.4.8 Explosive atmosphere

Explosive atmosphere certification

Commercial Formulation System is classified for use in explosive atmospheres as classified and field evaluated by a third-party. The explosive atmosphere classification is only valid when the system is used according to the safety instructions in this and relevant chapters. The classification and the IECEx number or ATEX certification is found on the system nameplate.

The system is certified according to explosive atmosphere standards as classified. For operation in environments to which ATEX, IECEx, or Hazardous Locations requirements apply, the system must not be modified and may only be connected to equipment certified for use in explosive atmosphere. All personnel using the equipment must read and understand this manual and be trained for operations in explosive atmosphere.

Explosive atmosphere and hazardous location classifications

Type	Classification
ATEX classification	 II 3 G Ex ec IIB T3 Gc
IECEx classification	Ex ec IIB T3 Gc Tamb 10°C to 30°C

Specific conditions for use

- For antistatic reasons, the system can only be cleaned by wiping with a damp cloth.
- The system must be installed in a location with a low risk of mechanical damage.
- The system must be installed in a location with a pollution degree of 2 or better.
- The system must be protected from UV-lights.
- The final power wiring installation shall be with suitable cable entries which hold a separate valid IECEx/ATEX Certificate of Conformity and with the same or better properties as this certification (See Table 10, IEC 60079-14:2013/EN 60079-14:2014).

9.5 Ordering information

Introduction

This section lists products and flow kits that are available for Commercial Formulation System.

Visit *cytiva.com* to find the latest information. For further information and quotes, contact your local sales representative.

Product codes

Name	Description	Product code
NanoAssemblr Commercial Formulation System	Standard system with 1 year warranty. ATEX/IECEx certified. Includes installation and training.	1002276
NanoAssemblr Commercial Formulation System service 1-year plan	Additional 1 year service covers defects, parts, repairs, and a preventive maintenance visit.	1002281
NxGen commercial development flow kit 12 L/h	For research use only (RUO). Flow kit assembly with a NxGen commercial cartridge 12 L/h	1002277
NxGen commercial development flow kit 48 L/h	For research use only (RUO). Flow kit assembly with a NxGen commercial cartridge 48 L/h	1002278
NxGen commercial manufacturing flow kit 12 L/h	Single-use flow kit assembly with a NxGen commercial cartridge 12 L/h	1002279
NxGen commercial manufacturing flow kit 48 L/h	Single-use flow kit assembly with a NxGen commercial cartridge 48 L/h	1002280
NCFS eIQOQ Protocol	Installation and Operational Qualification protocol	29798439
NCFS eIQOQ Performance	Service personnel to perform the Installation and Operational Qualification	29798426
NCFS IQOQ Consumable Kit	Consumables required to perform the Installation and Operational Qualification protocol	1002283
NCFS eRQ Protocol	Requalification protocol	29798442

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:			

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

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

cytiva

Give feedback on this document

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

cytiva.com

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

1002349 AA V:12 07/2024