

Xuri Cell Expansion System W25

Site Preparation Guide



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1 Introduction

Purpose of this document

The purpose of this document is to provide the information you need to fully prepare your site for the installation and testing of the system.

A site preparation checklist is included in this document.

You must return this checklist to Cytiva before Cytiva service personnel can install and test the system.



WARNING

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

Scope of this document

This Site Preparation Guide covers Xuri™ Cell Expansion System W25.

This Site Preparation Guide describes the following Xuri Cell Expansion System W25 units:

- Xuri Cell Expansion System W25 Base Unit unit
- Xuri Cell Expansion System W25 Pump unit
- Xuri Cell Expansion System W25 Cellbag™Control Unit (CBCU)
- Trays (10, 20, 50)
- Lids (10, 20, 50)

Feedback to Cytiva

Make sure to read the entire Site Preparation Guide and complete the Site preparation checklist in Chapter 3.

Return the completed Site preparation checklist to the Cytiva service office in your region. You will find E-mail address and fax numbers to the Cytiva service office in your region under:

cytiva.com/contact.

If your region is not listed, select the nearest region.

Assign personnel for site preparation tasks

The site preparation tasks listed in the following table can be assigned to more than one person at the customer site.

It is recommended that the same people assist the Cytiva service personnel during the subsequent installation process.

Personnel	Site preparation tasks		
Site preparation/ installation coordi- nator	 Review the site preparation guide for system requirements. Choose the site. Coordinate personnel and tasks. Coordinate the installation timing of the system with any domestic safety procedures and testings. Order the required materials. Schedule the installation and inform the relevant personnel of the installation date. 		
Laboratory personnel/ Primary users	Make sure that all customer-provided materials for the installation are present at the site.		
Facilities personnel	Make sure that the installation requirements are met for: Space at the installation site Environmental conditions Biosafety Ventilation and waste collection Electrical supply Gas and compressed air supply Safety and installation materials		

2 Site preparation overview

Introduction

Before the product is delivered, you must prepare the site according to the instructions in this chapter.

Select the site

The site must comply with national and international requirements for biosafety.

Personal protective equipment

No hearing protection is required on site.

General site requirements

The following requirements must be fulfilled at the location where the Xuri Cell Expansion System W25 will be installed:

- The room must have forced ventilation, adapted for use of CO₂, O₂ and N₂.
- The system units must not be exposed to sources of heat, such as direct sunlight.
- The bench must be clean, level, flat and sufficiently stable to withstand vibration from the rocking.
- Other vibrating equipment must not be present on the same bench, since vibrations might affect the weight reading.
- There must be no soft material, paper sheets or similar under the system, as this
 may block the ventilation inlet.
- There must be an easily accessible grounded power outlet close to the installation site of the system units.

Space requirements

A clean, flat and level working area on a stable laboratory bench is required. The bench must comply with the specifications in the following table.

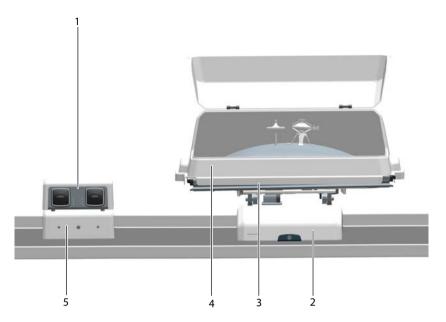
Parameter	Specification
Recommended bench area for operating Xuri Cell Expansion System W25	Recommended bench space is at least 80 cm deep and 180 cm wide.
Load capacity	The bench must be able to support the total weight of the system, including the filled Cellbag bioreactor. See <i>Dimensions and weight, on page 7</i> . If other optional instruments are installed, their weights must also be included.

Note: The power cord must be accessible and easy to disconnect.

In dual mode, the Xuri Cell Expansion System W25 CBCU and Xuri Cell Expansion System W25 Pump units must be placed on either side of the rocker to correspond with the \boldsymbol{L} and \boldsymbol{R} designations in the software.



Dimensions and weight



The table below lists the outer dimensions and weights of the bioreactor system units. The numbers in brackets relate to the numbers in the image.

System unit	Dimensions, W x D x H (mm)	Weight (kg)
Rocker (2)	404 x 560 x 205	24.0
CBCU (5)	276 x 360 x 117	4.8
Pump (1)	275 x 280 x 115	3.8
Tray 10 (3)	 475 x 430 x 60 System height with Tray 10 in tilt position (14° angle): Without lid: 315 mm With lid closed: 521 mm With lid unfolded: 815 mm 	4.5
Tray 20 (3)	740 x 480 x 70 System height with Tray 20 in tilt position (14° angle): Without lid: 315 mm With lid closed: 535 mm With lid unfolded: 842 mm	7.3

System unit	Dimensions, W x D x H (mm)	Weight (kg)
Tray 50 (3)	800 x 610 x 70 System height with Tray 50 in tilt position (14° angle): Without lid: 332 mm With lid closed: 554 mm With lid unfolded: 930 mm	9.5
Lid 10 (4)	511 x 554 x 294	1.7
Lid 20 (4)	823 x 557 x 308	3.0
Lid 50 (4)	881 x 686 x 326	4.0

The system units are shipped in delivery boxes with the following dimensions and weight.

Contents	Dimensions (mm)	Weight (kg)
Xuri Cell Expansion System W25, rocker	Expansion System	
Xuri Cell Expansion System W25 CBCU	330 x 380 x 195	7
Xuri Cell Expansion System W25 Pump	370 x 345 x 160	5
Tray 10	655 x 545 x 170	7
Tray 20	880 x 685 x 150	11
Tray 50	940 x 815 x 150	13
Lid 10	550 x 580 x 440	4
Lid 20	930 x 740 x 350	6
Lid 50	930 x 740 x 350	7

Environmental requirements

Xuri Cell Expansion System W25 is intended for indoor use only.

The installation site must comply with the following specifications:

Parameter	Specification
Ambient temperature, operation	15°C to 32°C
Relative humidity, operation	20% to 80%, non-condensing
Altitude, operation	Up to 2000 m
Atmospheric pressure	800 to 1060 mbar
Pollution degree	2

Note: For adequate temperature control, the ambient temperature must be at

least 5°C lower than the desired culture growth temperature.

Note: The load cells in the rocker are sensitive to changes in temperature. The

ambient temperature should be maintained as constant as possible for the

correct weight measurements.

Note: Adequate lifting equipment should be available at the site as dragging the

Xuri Cell Expansion System W25 can cause damage to the load cell.

A protected, indoor location is required for storage of the delivery boxes. The following storage requirements must be fulfilled for the unopened boxes.

Parameter	Allowed range
Ambient temperature, storage	-25°C to 50°C
Relative humidity, storage	5% to 95% humidity, non-condensing

Electrical requirements

Parameter	Specification
Supply voltage	100-120/200-240 V AC
Frequency	50/60 Hz
Max power	1500 VA
Number of wall outlets	 One for the Xuri Cell Expansion System W25, rocker unit One for the client computer One for the monitor
Mains connection	EU or US plug, outlet fused or protected by equivalent circuit breaker. UK mains cable available on request.

Parameter	Specification
Length of mains cable	2 m. Extension cables may be used if required.

Note:

The rocker is fitted with internal electrical fuses that are not user-replaceable.

System requirements

The table below lists the system specifications of Xuri Cell Expansion System W25.

Parameter	Data
System configuration	Benchtop system, external computer
Control system	UNICORN™ 7.0 or higher version
Rocker embedded PC operating system	Windows® 10 IoT Enterprise 2019 LTSC
Connection between PC and instrument	Ethernet or network

Computer requirements

Note:

The computer is either supplied as part of the bioreactor system delivery or obtained locally. The client computer equipment must be installed according to the manufacturer's instructions.

The table below lists client computer specifications for a UNICORN 7.x system for use with Xuri Cell Expansion System W25.

Xuri Cell Expansion System W25 is supplied with UNICORN 7.x, which requires Windows 7 or Windows 10. If you wish to use Xuri Cell Expansion System W25 with an earlier version of UNICORN, contact Cytiva for assistance.

Installation is supported for Windows 7 Professional, 32-bit or 64-bit, with Service Pack 1 or Windows 10 Professional 64-bit.

For information about compatibility between UNICORN versions and the supported operating systems and database versions see the UNICORN compatibility matrix at cytiva.com/UNICORNcompatibility.

Type of computer speci- fications	UNICORN Client	Database Server	Workstation installation	E-License Server
Min. free disk space	16 GB	10 GB	27 GB	500 MB

Type of computer specifications	UNICORN Client	Database Server	Workstation installation	E-License Server
Min. available RAM	4 GB	4GB	4 GB	2 GB
Disc format	NTFS	NTFS	NTFS	NTFS
Architecture	Quad-core processor or 4 logical processor	Quad-core processor or 4 logical processor	Quad-core processor or 4 logical processor	Multi-core processor

Note:

- UNICORN is tested using the English (U.S.) Code 1033 operating system language version. Using other language versions of the operating system may cause errors.
- A screen resolution of 1280x1024 or higher is recommended. Parts of the UNICORN user interface may not be displayed properly using a lower resolution.
- Changing the default font and changing the font size from 100% in Windows may cause problems in the UNICORN user interface.
- The Windows basic color scheme is recommended.
- Using the Windows 7 or Windows 10 Aero color scheme is not recommended.
- Windows power save features should be turned off to avoid conflicts with system operations.
- UNICORN is not compatible with the Windows 7 or Windows 10 feature
 High DPI Awareness, which allows the graphic user interface to be
 scaled. The interface scale must remain at 100% to avoid issues with clipping and misaligning of parts of the UNICORN user interface. Normally,
 the scale is set at 100% by default.

Uninterruptible Power Supply Requirements

An Uninterruptible Power Supply (UPS) can postpone power failure, which allows time for a controlled shut-down of the bioreactor system and prevents data loss.

For UPS power requirements, the power consumption of each Xuri Cell Expansion System W25 (1500 VA) must be taken into consideration. See the system specifications in *Xuri Cell Expansion System W25 System Handbook*. The specifications for the client computer and monitor must be taken into account.

Refer to the UPS manufacturers' documentation for other details.

The UPS should be sufficient to maintain the system until a backup generator can take over.

It is recommended to connect a UPS during set up.

User-supplied accessories and consumables

The following equipment must be supplied by the user:

Equipment	Specification
Pump tubing	1.5 m long
Calibration weights or suitable container to hold equivalent volume of water	10 L tray: 3 kg, 5 kg20 L tray: 5 kg, 10 kg50 L tray: 13 kg, 25 kg
Gas regulators on all gas supplies	To make sure the pressure is maximum 1.5 bar
Graduated cylinders	• 100 mL • 400 mL
Access to water	For testing temperature, pumps, and weight
Air dryer	When air-in is supplied by compressed air
Personal Protective Equipment (PPE) as required	Gloves, lab coats, etc.

Heat output

The following table lists the heat output data.

Component	Heat output
Bioreactor system, including the rocker unit, CBCU and pump.	Maximum 1500 W

Gas supply

The following table lists the gas supply required for each installed CBCU. ¹

When using multiple CBCUs, gas pressure at inlets for each CBCU must be maintained at the listed pressure while active. Required gas flow is per active CBCU, and total flow must be multiplied based on the number of CBCUs that must be active at the time.

Gas	Pressure (bar)	Flow (L/min) Normal mode	Flow (L/min) Fast fill mode
Compressed air/N ₂	1.0 to 1.5	1.3	3.5
CO ₂	1.0 to 1.5	0.2	0.5
O ₂	1.0 to 1.5	0.7	1.7

Quality of gases

Air & gases (O_2,CO_2,N_2) supplied to CBCU must be dust free and moisture free. For gases (O_2,CO_2,N_2) it is recommended to use close to 100% concentration.

3 Site preparation checklist

Introduction

Read the previous chapters in this Site Preparation Guide before completing the checklist.

Complete the checklist in this chapter to make sure that all necessary preparations have been made for the installation of Xuri Cell Expansion System W25.

You must send the completed checklist to a Cytiva office before Cytiva service personnel can install Xuri Cell Expansion System W25. See details in Chapter 1.

Note:

Completion of the checklist is also mandatory if an already installed/commissioned Xuri Cell Expansion System W25 is moved/relocated to a different site.

Checklist

Requirement		YES	NO	N/A	Comment/specify
Gen	eral				
	n was the Xuri Cell Expansion System system received (month/year)?				
Will the Cytiva service personnel be required to take site EHS (Environment, Health and Safety) or security training before doing the installation?					
Assigned personnel					
Personnel are assigned as specified.					
Site	Site selection				
	Site complies with requirements for biosafety				
	General site requirements are fulfilled				
Spa	Space requirements				
Spac	Space is available as specified.				
Envi	Environmental requirements				
1	The proper environmental conditions are fulfilled as specified.				

Requirement	YES	NO	N/A	Comment/specify
Ambient temperature				
Relative humidity				
Atmospheric pressure				
Forced ventilation				
Electrical requirements				
Electrical requirements are fulfilled as specified.				
Number of wall outlets: 3				
One outlet for the Xuri Cell Expansion System W25, rocker unit				
One outlet for the client computer				
One outlet for the monitor				
Computer requirements				
A client computer has been purchased and received.				
Will the Xuri Cell Expansion System W25 system be connected to a network?				
Is there on-site IT support available if needed?				
Are the operating system requirements fulfilled?				
User supplied equipment				
Personal Protective Equipment (PPE) as required, (e.g., gloves, lab coats, etc.)				
Pump tubing, 1.5 m				

Requirement	YES	NO	N/A	Comment/specify
Calibration weights				
 10 L tray: 3 kg, 5 kg 20 L tray: 5 kg, 10 kg 50 L tray: 13 kg, 25 kg or suitable container to hold equiva- 				
lent volume of water				
Gas regulators on all gas supplies, maximum 1.5 bar				
Graduated cylinder, 100 mL				
Graduated cylinder, 400 mL				
Access to water				
Air dryer				

Additional information

Customer contact information

Date (dd-mmm-yyyy)			
Company/Customer name			
Name			
Address			
Email			
Phone number			
Customer experience level	Beginner	Intermediate	Advanced



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Cellbag bioreactors with integrated optical sensors are sold under a sublicense from Sartorius Stedim Biotech under US patent numbers 7,041,493 and/or its foreign equivalents, and please visit http://www.pall.com/patents

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

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