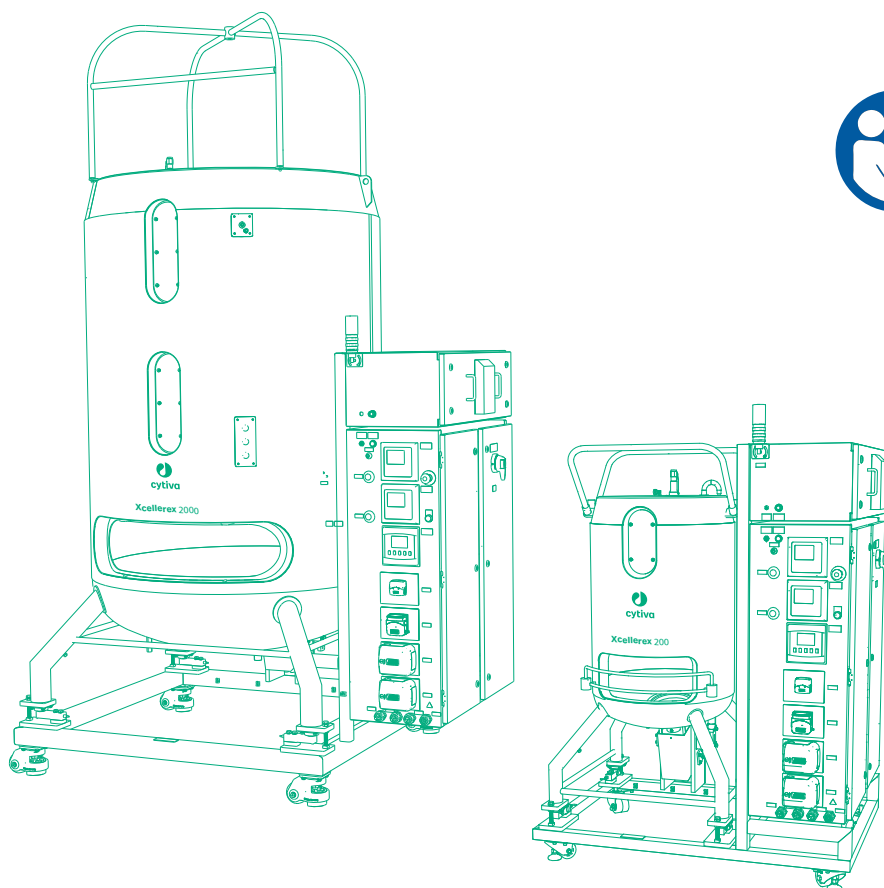


# **Xcellerex™ XDR-50 to 2000**

## **Bioreactor Systems**

### **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 prepare your site for the installation of the product.

A site preparation checklist is included in this document.

## Scope of this document

This Site Preparation Guide covers all variants of standard Xcellerex™ XDR-50 to 2000 Bioreactor Systems.

## Preparation

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

If Cytiva support is needed, return the completed Site preparation checklist to the Cytiva service office in your region. You will find the email address to the Cytiva service office at [cytiva.com/contact](https://www.cytiva.com/contact). If the applicable 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.

Personnel	Site preparation tasks
Site preparation/ installation coordinator	<ul style="list-style-type: none"> <li>• Review the site preparation guide for safety information and system requirements.</li> <li>• Choose the site.</li> <li>• Coordinate personnel and tasks.</li> <li>• Coordinate the installation timing of the system with any domestic safety procedures and testings.</li> <li>• Order the required materials.</li> <li>• Schedule the installation and inform the relevant personnel of the installation date.</li> </ul>
Laboratory personnel/ Primary users	<ul style="list-style-type: none"> <li>• Review the safety information.</li> <li>• Make sure that all customer-provided materials for the installation are present at the site.</li> </ul>
Facilities personnel	<ul style="list-style-type: none"> <li>• Make sure that the installation requirements are met for:               <ul style="list-style-type: none"> <li>- Space at the installation site</li> <li>- Environmental conditions</li> <li>- Biosafety</li> <li>- Ventilation and waste collection</li> <li>- Electrical supply</li> <li>- Safety and installation materials</li> <li>- Lifting and moving equipment, if applicable</li> </ul> </li> </ul>
Electrical engineer	<ul style="list-style-type: none"> <li>• Confirm that the electrical supply at the site meets the required electrical specifications.</li> <li>• Confirm that the electrical plugs intended for use with the equipment meet the required electrical specifications.</li> <li>• Plan to verify that the mains power plug is installed correctly.</li> </ul>

## 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

Select a site that complies with national and international requirements for biosafety.

### System overview

XDR-50 to 2000 Bioreactor Systems are stirred-tank bioreactors, intended for cell culture and microbial fermentation processes used in researching, developing or manufacturing biologics or drugs.

XDR-50 to 2000 Bioreactor Systems are intended for indoor use only.

XDR-50 to 2000 Bioreactor Systems consist of following parts:

- XDR vessel
- I/O Cabinet
- Gas supply cabinet
- Condenser assembly (optional)
- X-Station
- Temperature control unit (TCU)

The cell cultivation process is managed using a free-standing control unit called X-Station.

A separate temperature control unit is necessary for vessel jacket temperature regulation. The TCU can be purchased from Cytiva or supplied by the customer.



Part	Description
1	Temperature control unit (TCU)
2	XDR bioreactor
3	X-Station

## Environmental conditions

The following general requirements must be fulfilled:

- The room must have exhaust ventilation.
- The instrument should not be exposed to corrosive gases.
- The instrument should not be exposed to sources of heat, such as direct sunlight.
- Dust in the atmosphere should be kept to a minimum.
- Strong magnetic or electric fields should be avoided.
- The instrument should not be exposed to vibrations.

## Space requirements

The following general site requirements must be fulfilled at the location where the XDR-50 to 2000 Bioreactor System will be installed:

- The floor must be level and without irregularities to allow equal distribution of the system weight over all wheels.
- At least 100 cm (40 inches) free working space is needed around each unit during installation.
- For convenient working conditions during the use, sufficient space must be provided on all sides of the system when installed at the intended production location.

The following space requirements must be fulfilled at the location where the XDR-50 to 2000 Bioreactor System will be installed:

XDR vessel size	Minimum floor to ceiling height <sup>1</sup>	Minimum door height <sup>2</sup>	Minimum door width <sup>2</sup>
50 L (standard design)	275 cm (108")	200 cm (78½")	121 cm (47½")
50 L (split frame design)	275 cm (108")	200 cm (78½")	88 cm (34½")
200 L	297 cm (117")	200 cm (78½")	120 cm (47")
500 L	287 cm (113")	200 cm (78½")	129 cm (50½")
1000 L	361 cm (142")	242 cm (95")	145 cm (57")
2000 L	410 cm (161¼")	277 cm (109")	162 cm (63½")

<sup>1</sup> Including 63.5 cm (25") clearance between the instrument and the ceiling.

<sup>2</sup> Including 13 cm (5") clearance.

**Note:** Prepare sufficient space for the X-Station and the TCU.

The following illustration shows the dimensions of the X-Station.



**Dimensions and weight**

The following table shows the dimensions and weight of the XDR-50 to 2000 Bioreactor Systems.



Property	System	Value
Dimensions (Width × Height × Depth)	X-Station	601 × 1466 × 798 mm (23 <sup>5</sup> / <sub>8</sub> × 57 <sup>3</sup> / <sub>4</sub> × 31 <sup>1</sup> / <sub>2</sub> inches)
	50 L bioreactor (single frame design)	149 × 211 × 123 cm (58 <sup>1</sup> / <sub>2</sub> × 82 <sup>3</sup> / <sub>4</sub> × 42 <sup>1</sup> / <sub>8</sub> inches)
	50 L bioreactor (split frame design)	162 × 211 × 123 cm (63 <sup>3</sup> / <sub>4</sub> × 82 <sup>3</sup> / <sub>4</sub> × 42 <sup>1</sup> / <sub>8</sub> inches)
	200 L bioreactor	148 × 233 × 107 cm (58 <sup>1</sup> / <sub>8</sub> × 91 <sup>3</sup> / <sub>8</sub> × 41 <sup>3</sup> / <sub>4</sub> inches)
	500 L bioreactor	170 × 224 × 116 cm (66 <sup>5</sup> / <sub>8</sub> × 88 × 45 <sup>1</sup> / <sub>2</sub> inches)
	1000 L bioreactor	181 × 297 × 132 cm (70 <sup>7</sup> / <sub>8</sub> × 116 <sup>5</sup> / <sub>8</sub> × 51 <sup>3</sup> / <sub>4</sub> inches)
	2000 L bioreactor	197 × 347 × 149 cm (77 <sup>1</sup> / <sub>2</sub> × 136 <sup>1</sup> / <sub>4</sub> × 58 <sup>1</sup> / <sub>2</sub> inches)
System weight (empty)	X-Station	146 kg (65.7 lb)
	50 L bioreactor (single frame design)	466 kg (1028 lb)
	50 L bioreactor (split frame design)	550 kg (1213 lb)
	200 L bioreactor	570 kg (1257 lb)
	500 L bioreactor	669 kg (1475 lb)
	1000 L bioreactor	874 kg (1927 lb)
	2000 L bioreactor	1135 kg (2502 lb)

**Note:** Refer to the manufacturer's manual for the TCU dimensions and weight.

## Environmental specifications

The installation site must comply with the following specifications:

Process	Parameter	Specification
Operation	Allowed location	Indoor use only
	Ambient temperature	5°C to 30°C

Process	Parameter	Specification
	Relative humidity	≤ 90%, non-condensing
	Altitude	Up to 2000 m
	Pollution degree of the intended environment	Pollution degree 2
Storage	Ambient temperature	4°C to 40°C
	Relative humidity	< 80%, non-condensing
Transportation	Ambient temperature	-25°C to 60°C
	Relative humidity	5% to 95%

## Grounding and protective earth

- The protective earth wire must be connected to system ground.
- Ground impedance must conform to the requirements of national and local industrial safety regulations and/or electrical codes.
- Because the earth leakage current exceeds 10 mA on XDR-50 to 2000 Bioreactor Systems with supply voltage rating of 220 V AC ± 10%, these systems are provided with a pin and sleeve-type of plug meeting IEC 60309 standard.
- The integrity of all ground connections must be periodically checked.

## Mains cable

The customer must install a mains disconnect switch on the wall, to allow immediate disconnection of all power from the system. For systems with a supply voltage rating of 220 V AC ± 10% the customer must also install an IEC 60309 socket connection.

**Note:** *If the customer replaces the plug supplied with the system, and uses a non-IEC 60309 plug instead, the compliance rating of the system is no longer valid.*

The mains cable is supplied by Cytiva. If the customer replaces the mains cable, the replacement cable must meet the mains cable specifications as shown in the following table.

The customer must install an electrical plug on the mains cable of Xcellerex bioreactor (applicable to 110 V AC instruments only), and follow the wire color code shown in the Cytiva electrical drawing. The electrical plug must comply with local regulations, and the installation must be performed in accordance with local codes. For instructions on how to verify if the mains power plug installation is done correctly, refer to the applicable *Operating Instructions*.

The mains power supply cable wires are color or number coded. They must be connected to the corresponding terminals in a connector compatible with IEC 60309.

Number of conductors	AWG <sup>1</sup>	Cable outer diameter	Maximum operating voltage	Length
3	12	12.7 to 15.9 mm	600 V RMS	5 m

<sup>1</sup> AWG: American wire gauge

The cable must be installed according to national regulations.

## Electrical power

The following table specifies the power requirements for XDR-50 to 2000 Bioreactor Systems.

Parameter	Requirement
Supply voltage, XDR-50 to 2000 Bioreactor Systems	<ul style="list-style-type: none"> <li>110 V AC <math>\pm</math> 10%, 1 phase, 50/60 Hz, 14 A</li> <li>220 V AC <math>\pm</math> 10%, 1 phase, 50/60 Hz, 6 A</li> </ul>
Supply voltage, X-Station	<ul style="list-style-type: none"> <li>110 V AC <math>\pm</math> 10%, 1 phase and protective earth, 50/60 Hz, 2.9 A</li> <li>220 V AC <math>\pm</math> 10%, 1 phase and protective earth, 50/60 Hz, 1.5 A</li> </ul>
Number of electrical outlets	Three outlets for the following units <sup>1</sup> : <ul style="list-style-type: none"> <li>X-Station</li> <li>Bioreactor</li> <li>TCU</li> </ul>
Recommended backup power supply	Uninterruptible power supply (UPS)

<sup>1</sup> Additional outlets are required, if optional equipment (for example external pumps) is purchased with the system.

## Gas supply

The customer must supply semi-rigid polyethylene, flexible polyvinyl chloride, or flexible polypropylene tubing from the room gas outlet to quick disconnect fittings of the gas supply cabinet. Nitrogen is not required for many processes but is recommended for dissolved oxygen (DO) calibration.

The following table describes the requirements regarding gas supply. The requirements depend on the disposable bag design.

Parameter	Requirement
Gas pressure and capacity	<ul style="list-style-type: none"> <li>Compressed air: 303 kPa (3.03 bar, 44 psig), 0–100 SLPM</li> <li>Oxygen: 303 kPa (3.03 bar, 44 psig), 0–100 SLPM</li> <li>Carbon dioxide: 303 kPa (3.03 bar, 44 psig), 0–20 SLPM</li> <li>Nitrogen: 303 kPa (3.03 bar, 44 psig), 0–25 SLPM</li> </ul>
Gas inlet dimensions	<ul style="list-style-type: none"> <li><b>AIR INLET</b>, o.d. ½" or ¼"</li> <li><b>O<sub>2</sub> INLET</b>, o.d. ½" or ¼"</li> <li><b>CO<sub>2</sub> INLET</b>, o.d. ¼"</li> <li><b>N<sub>2</sub> INLET</b>, o.d. ¼"</li> <li><b>PILOT AIR INLET</b>, o.d. ¼"</li> </ul> <p><b>Note:</b> <i>Unused gas inlets should be plugged.</i></p>
Gas supply tubing	<p>Semi-rigid polyethylene tubing, pressure rated 1000 kPa (10 bar, 150 psig)</p> <ul style="list-style-type: none"> <li>Compressed air: o.d. ½" or ¼"</li> <li>Oxygen: o.d. ½" or ¼"</li> <li>Carbon dioxide: o.d. ¼"</li> <li>Nitrogen: o.d. ¼"</li> </ul>
Gas outlet dimensions	<ul style="list-style-type: none"> <li><b>SPARGER 1 OUTLET</b>, o.d. ½" or ¼"</li> <li><b>SPARGER 2 OUTLET</b>, o.d. ½" or ¼"</li> <li><b>HEADSPACE OUTLET</b>, o.d. ½" or ¼"</li> <li><b>PINCH VALVE PILOT</b>, o.d. ¼"</li> </ul> <p><b>Note:</b> <i>If the external valve is not used, the <b>PINCH VALVE PILOT</b> should be plugged.</i></p>

## Water supply

The following types of water are required for filling the bioreactor (full volume), vessel jacket/temperature control unit, and disposable bags:

- Purified Water (PW)
- Chilled Water Supply (CWS), depending on temperature control unit configuration
- Chilled Water Return (CWR), depending on temperature control unit configuration

Disposable bags can even utilize Water for Injection (WFI).

## **Temperature regulation**

A temperature control unit (TCU) is required to control the temperature of the bioreactor.

Liquid cooled temperature control units (TCU) require water or chilled water connections.

Contact a Cytiva service representative to discuss a TCU solution.

# 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 your system.

## Checklist

Requirement	YES	NO	N/A	Comment/specify
<b>General</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Has the system been received? If yes, specify when (month/year).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Will the Cytiva service personnel be required to take site EHS (Environment, Health and Safety) or security training before doing the installation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Assigned personnel</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Have personnel been assigned as specified? See <a href="#">Assign personnel for site preparation tasks, on page 3</a> .	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Does the personnel experience level with the product correspond to:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
New user	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Intermediate user	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Advanced user	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Will the personnel require training on how to use the system?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Site selection</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Does the site comply with requirements for biosafety?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are the general site requirements fulfilled?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Environmental requirements</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Requirement	YES	NO	N/A	Comment/specify
Are the proper environmental conditions fulfilled as specified? See <a href="#">Environmental specifications, on page 9</a> .	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Ambient temperature	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Relative humidity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Atmospheric pressure	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Forced ventilation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Space requirements</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Is the specified space available?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Electrical requirements</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are the electrical requirements fulfilled as specified? See <a href="#">Electrical power, on page 11</a> .	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Is the electrical plug for the mains cable of the bioreactor purchased? The plug must comply with local regulations.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Has a qualified electrical engineer confirmed the electrical supply at the site, and the electrical plugs intended for use with the equipment meet the required electrical specifications?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Number of wall outlets:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
One outlet for the X-Station	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
One outlet for the bioreactor	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
One outlet for the TCU	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Outlets for additional equipment (optional)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Gas supply</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are the requirements for gas supply fulfilled as specified?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Gas supply tubing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Gas pressure and capacity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Gas inlet dimensions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Gas outlet dimensions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>User supplied equipment</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Requirement	YES	NO	N/A	Comment/specify
Is Personal Protective Equipment (PPE) available (e.g., gloves, lab coats, etc.)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Does the lifting and moving equipment meet the requirements?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Is a temperature control unit (TCU) purchased?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are consumables and accessories (e.g., disposable bag, probes) ordered?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are containers and tubing ordered? (To allow filling of bioreactor, vessel jacket/TCU and disposable bags if water is not available in the testing room.)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>User supplied consumables</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Water as specified	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Gas: Air, CO <sub>2</sub> , O <sub>2</sub> , and N <sub>2</sub>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
pH calibration standards (e.g., pH 4, 7 and 10)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
pH 9.21 calibration standard (for dissolved CO <sub>2</sub> option)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>General lab equipment</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Small containers for pH calibration, typically 50 mL conical tubes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Wipes, spray bottle and waste containers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
pH meter	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Drain facility for waste collection	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Equipment to connect tubing</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Tubing clamps	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Barb fittings	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Cable ties	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Other documentation</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Factory Acceptance Test (FAT)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Product Documentation package (Turnover Package) (ToP)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Installation Qualification/Operational Qualification (IQ/OQ) printed, reviewed and signed, as applicable	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Additional information

Customer contact information

Date (dd-mmm-yyyy)			
Company/Customer name			
Name			
Address			
Email			
Phone number			
Customer experience level	Beginner <input type="checkbox"/>	Intermediate <input type="checkbox"/>	Advanced <input type="checkbox"/>

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