

Xcellerex™

X-platform bioreactors

CELL GROWTH AND EXPANSION

Designed to address your cell culture needs, Xcellerex™ *X-platform* bioreactors combine high performance and flexibility with the reliability of Xcellerex™ single-use technologies.

Benefits of Xcellerex™ *X-platform* bioreactors:

- Streamlined operations owing to standardized, configurable system
- Application-ready bag designs for easier process optimization
- Standardized bag assemblies for shorter delivery times
- Support for high-density cell cultures with the novel impeller, sparger and vessel design
- Low-shear mixing capabilities for lower cell density applications
- Coordinated process control via Figurate™ automation solutions
- Modular design for easier incorporation in cleanroom or pilot facilities
- Simplified scalability with online Bioreactor Scaler tool

Xcellerex™ *X-platform* bioreactors

Designed to meet your process needs today and in the future, *X-platform* bioreactors build on the legacy of Xcellerex™ single-use technologies. We've designed a new sparger and impeller to meet the requirements for a wide range of applications — from high-cell-density monoclonal antibody (mAb) processes to low-cell-density processes. We've built the system with configurable hardware and application-ready cell culture bags, so if your process needs change, your *X-platform* bioreactor system can change with them.

X-platform bioreactors consist of three separately housed components: the bioreactor vessel (Fig 1), a cabinet assembly, and the human machine interface (HMI). This modular approach enables you to arrange the system to fit your space, without the need to customize hardware or single-use bag assemblies. The bioreactor door opens wide to simplify bag installation, and



Fig 1. Xcellerex™ X-200 bioreactor. The X-200 has a 200 L bioreactor vessel.

novel cable management solutions facilitate ease of use. The cabinet assembly houses all power, gas, and liquid management and sensor components, which can be positioned on either side of the bioreactor. Users operate the control software (Figurate™ automation powered by PlantPAx® DCS) via the HMI, which features an ergonomic design suitable for use in cleanroom environments.

Bioreactor vessel

Xcellerex™ *X-platform* bioreactor systems are initially available in two vessel sizes – 50 L maximum working volume (*X-50*) and 200 L maximum working volume (*X-200*). Both are designed with a 5:1 turndown ratio.

We used computational fluid dynamic (CFD) modeling to determine the optimal placement of the drive unit, baffles, and liquid addition lines. The drive unit is center mounted on the bottom of the vessel, resulting in a broad power input range and predictable scalability. The drive unit, together with a latching mechanism for the bag impeller base plate, ensures proper bag alignment and facilitates installation.

The size, shape, and profile of the impeller and sparge are optimized for mixing and mass transfer of gases and cell culture media, supporting a wide range of cell densities. This makes the system equally well suited to low-cell density applications, mAb seeding, fed-batch, and perfusion cultures. The sparge design includes three main elements for oxygen mass transfer and an optional single element for metabolic CO₂ mitigation. Predefined hardware configurations are ready to meet specific growth requirements.

Multilevel probe support accommodates multiple sub-surface probes and ports. The support is height-adjustable to enable correct positioning of the probes in the bioreactor chamber.

Bag installation is quick and easy with the wide-opening door (Fig 2). The graduated viewing window makes it easy to estimate how much liquid is in the bioreactor bag. Conventional multi-use probes are installed with the probe sheath (Fig 3) and disposable aseptic connectors. You can install 4–8 probes, depending on the configuration of the bag, as well as a temperature sensor.



Fig 2. Xcellerex™ *X-200* bioreactor and full opening door.

The *X-platform* bioreactors include sensors for electrochemical pH, polarographic and optical dissolved oxygen, dissolved CO₂, viable cell density (permittivity), pressure, and temperature. Calibration is managed via the HMI using native probe calibration software. Wireless connectivity simplifies probe calibration (Fig 4). In-process data acquisition is via Modbus.



Fig 3. Click-in probe sheath.



Fig 4. Wireless probe transmitter.

The *X-platform* will automatically switch to a new filter using the pinch valves when the pressure in the head space reaches a maximum threshold. Up to three exhaust filters and exhaust filter heaters (Fig 5) may be configured to support a variety of processes, from batch to perfusion. Long duration runs or runs where filter fouling may be a concern may benefit from multiple filters (and the corresponding pinch valves, which automatically switch to another filter when the current one becomes clogged).

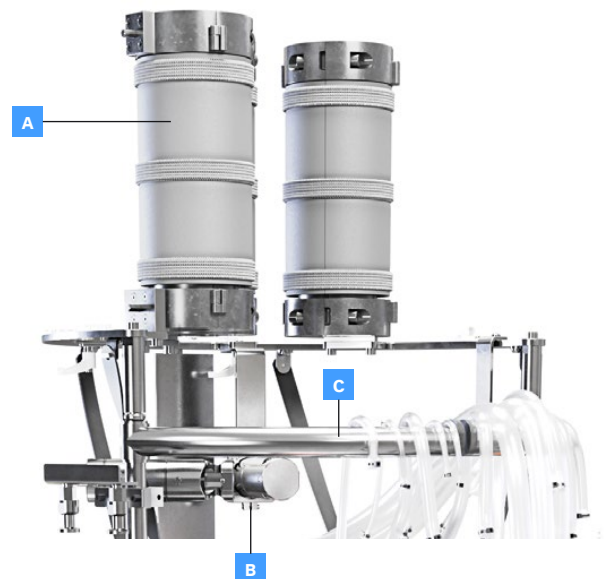


Fig 5. Exhaust filter heaters (A), pinch valves (B), and tubing support arm (C).

Four standard bag designs (Table 1) support security of supply and provide application-specific features and functions for use in basic applications, such as batch cultures, to more complex perfusion operations. The bags are built with industry-proven ReadyKleer™ film and are shipped with packaging, labeling, and dedicated instructions.

Adjustable arms (Fig 5C) support liquid lines and prevent kinking. The tubing guide bundles and routes tubing to the left, right, or center, depending on your requirements. The sparge line is routed through the bag between the front-facing entry and the fixed mounts on the tubing manager at the top of the system.

Table 1. Four standard bag configurations are available with Xcellerex™ X-platform bioreactor systems

Name	Description
Fed-batch I	Most basic bag type. Suitable for simple process (e.g. cell expansion) that require few sensors, few liquid additions, simple sparging.
Fed-batch II	Similar to Fed-batch I but allows more complex processes. The bag includes additional exhaust ports, sensors, liquid addition possibilities, and secondary sparging.
Perfusion I	Suitable for simple perfusion processes. Similar to Fed-batch II, and also includes ports for attachment to a perfusion system.
Perfusion II	Most advanced bag type, suitable for demanding perfusion applications. Includes all available options.

Cabinet assembly

The modular, integrated cabinet assembly (Fig 6) design enables flexibility. The cabinet can be positioned on either side of the bioreactor vessel. Four subsystems make up the cabinet assembly: power, fluid/gas management, I/O and automation. The cabinet can also be configured for a wide range of gas and liquid flow rates.



Fig 6. Front view of cabinet assembly showing pump heads.

Pumps

For liquid management, up to four built-in peristaltic pumps with choices of Watson-Marlow pump head sizes 114DV, 313D, and 520R2 can be added. Each pump has its own priming switch for easier setup and preparation for cell culture runs. The pump assemblies are modular to allow on-site changes when process requirements change. The system is also compatible with external Watson-Marlow pump models 530EnN, 630EnN, and 730EnN.

Gas management

X-platform bioreactors incorporate five high-performing mass-flow controllers (MFCs). Each MFC has a 250:1 turndown ratio, offering a wide range of gas flow rates to support a broad range of process requirements. Regulators with gauges set the incoming gas pressure for process gases and instrument air.

Manual shut-off valves allow isolation of the system from main gas supplies for maintenance and idle time.

Alarms, connectivity and communication

The alarm stack includes audio and visual system status indicators and is available as a standard option, which is particularly useful in multi-system environments.

All input and output connections are on the back of the cabinet assembly (Fig 7) for easy management of cables and gas lines.



Fig 7. Rear view of cabinet assembly with input and output connections.

The system and subsystems communicate by Ethernet/IP. Cable lengths of 5 m and 10 m are available to facilitate equipment placement for efficient operation.

Non-Ethernet/IP connections are located together and include agitator power and signal, process temperature, and load cells. Modbus sensor connectors from the bioreactor are consolidated into a single cable that runs back to the cabinet assembly.

Human-machine interface (HMI)

The ergonomically designed HMI (Fig 8) features a 21.5 in. color touchscreen, industrial keyboard, and mouse designed for ergonomic use in a cleanroom environment. The setup is ingress protection rated IP55 and features locking 304SS stainless steel casters. Users can easily adjust the keyboard and screen height for comfort.

Native calibration software is included for probes and sensors. USB ports are used for wireless communication between the HMI and the probes and sensors during calibration procedures.



Fig 8. Front view of HMI.

Automation

Xcellerex™ X-platform bioreactors run on Figurate™ automation powered by Rockwell Automation’s PlantPAX® distributed control system (DCS). The process control environment consists of three main elements:

- A Process Automation System Server (PASS) to host displays, alarms, and data connections to controller.
- An interactive graphical display (HMI) (Fig 9).
- ControlLogix® controllers to support continuous process and batch applications.

Within the PlantPAX® system, there are several software applications:

- FactoryTalk View allows users to monitor and control manufacturing.
- FactoryTalk Batch allows users to specify and execute procedures and stores activity information.
- FactoryTalk Historian software provides data capture, management, and analytical capabilities.

Bioreactor Scaler tool

Whether you are scaling up from a small bioreactor or looking to transfer from an Xcellerex™ XDR bioreactor to an X-platform system, the Bioreactor Scaler (Fig 10) makes the process simple. Just enter your existing process parameters and the scaler will provide you with the operating conditions.

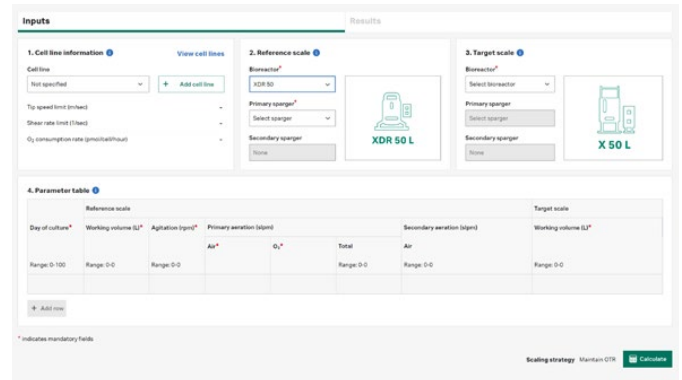


Fig 10. A screenshot of our online Bioreactor Scaler tool.

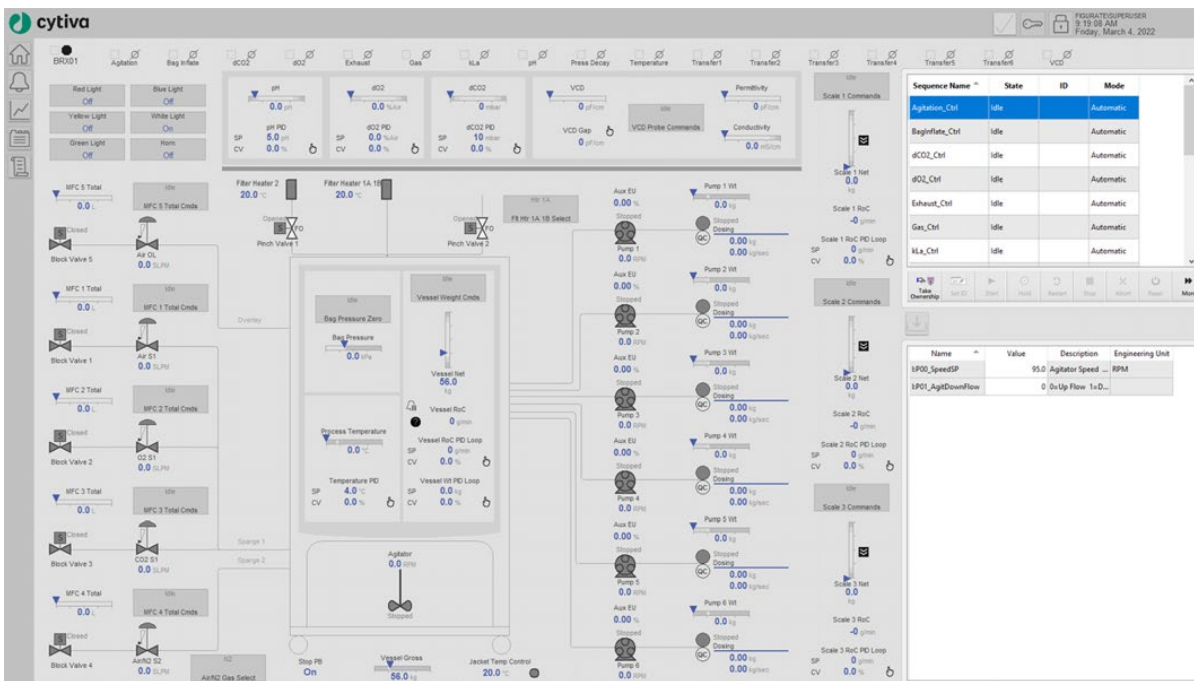


Fig 9. Interactive graphics display.

OptiRun™ Service Solutions

Regulatory authorities require systems to be qualified and maintained within specifications during use in process scale-up and GMP-manufacturing. Our OptiRun™ Service Solutions offer a comprehensive range of services (Table 2) throughout the product's life cycle to support your technology, processes, and people.

Table 2. OptiRun™ Service Solutions for Xcellerex™ X-platform bioreactors

Services	Description
Equipment installation	Installation can be performed by trained Cytiva specialists
Online equipment management	My Equipment online equipment management tool keeps track of your instrument service contracts, service records, and your installed base of Cytiva instruments
Preventive maintenance	Replacement of wear-and-tear parts and functional testing to ensure continuous performance of your instrument
IQOQ and Re-qualification	Standard and custom qualification services for Cytiva equipment throughout its life cycle, including IQ/OQ, RQ, and continuous verification
Instruments upgrades	Hardware and software upgrades to keep your equipment state-of-the-art during its life cycle
Repairs	Field, remote and mail-in repairs are available depending on your instrument type and environment
Digital services	A range of digital solutions, from remote assistance to network installation and virtual support and trainings
Spare parts	High quality spare parts for use in GxP environment; parts security of supply consultancy
Relocation support	Preparing your equipment for move and re-installing it in its new location
Service plans	A range of plans to support your operations and instrument performance

System specifications

	X-50	X-200
Max. working volume (L)	50	200
Min. working volume (L)	10	40
Volume turndown ratio	5:1	5:1
Vessel	Jacketed 304 SS vessel with opening door	
Filter heat assembly	1 as standard	
Additional filter heater assemblies	Up to 3 total	
Impeller type	6B-R50	6B-R50
Agitation speed downflow (RPM)	0–285	0–185
Agitation speed upflow (RPM)	0–285	0–215
Enclosure protective class*	IP55	IP55

Process instrumentation	X-50	X-200
pH probes	2	2
DO probes	2	2
CO ₂ probes	1	1
VCD sensor	1	1
MFC	5	5
MFC range (SLPM) [†]	0.1–10	0.1–40
Internal pumps (up to 4)	Watson-Marlow 114DV, 313D, and 520R2	
External pumps (optional)	Watson-Marlow 530EnN, 630EnN, and 730EnN	
Load cells	4	4

* for the bioreactor, cabinet assembly and HMI

[†] The maximum MFC set point value for both bioreactor sizes is shown in the table. Specific MFCs have different SP values, based on their function.

System dimensions

50 L vessel (without step platform) (W × D × H)	Top frame and exhaust filter heaters included: 837 × 750 × 2013 mm (33.0 × 30.9 × 79.3 in.)
	Top frame and exhaust filter heaters excluded: 837 × 750 × 1314 mm (33.0 × 30.9 × 51.7 in.)
50 L vessel (with step platform) (W × D × H)	Top frame and exhaust filter heaters included: 837 × 1060 × 2013 mm (33.0 × 41.7 × 79.3 in.)
	Top frame and exhaust filter heaters excluded: 837 × 1060 × 1314 mm (33.0 × 41.7 × 51.7 in.)
200 L vessel (W × D × H)	Top frame and exhaust filter heaters included: 877 × 963 × 2536 mm (34.5 × 37.9 × 99.9 in.)
	Top frame and exhaust filter heaters excluded: 877 × 963 × 1566 mm (34.5 × 37.9 × 61.7 in.)
Cabinet assembly (W × D × H)	Audible visual indicator included: 802 × 1129 × 1554 mm (31.6 × 44.4 × 61.2 in.)
	Audible visual indicator excluded: 802 × 1129 × 1151 mm (31.6 × 44.4 × 45.3 in.)
HMI (W × D × H)	710 × 685 × 1717 mm (28.0 × 27.0 × 67.6 in.)

System weights

50 L vessel (without step platform)	236 kg (520 lb)
50 L vessel (with step platform)	248 kg (546 lb)
200 L vessel	336 kg (741 lb)
Cabinet assembly	209 kg (461 lb)
HMI	70 kg (154 lb)

Bioreactor bag specifications

Bags for Xcellerex™ X-50 bioreactor

Bag port ⁵	Intended function	Tubing size ³ (ID × OD), inches	Tubing length ⁴ , inches (mm)	Terminal connector	Product code			
					Fed-batch I (29696537)	Fed-batch II (29696536)	Perfusion I (29696535)	Perfusion II (29696534)
A	Exhaust 2	1/2" × 3/4"	10.0 (255)	ReadyMate™, 1/2"	●	●	●	●
B	Exhaust 1	1/2" × 3/4"	7.0 (180)	ReadyMate™, 1/2"	●	●	●	●
C	Exhaust 3	1/2" × 3/4"	10.0 (255)	ReadyMate™, 1/2"	●	●	●	●
D	Overlay	1/4" × 7/16"	26.0 (660)	Mini-Triclamp	●	●	●	●
	Overlay w/ redundant pressure sensor	1/4" × 7/16"	26.0 (660)	Mini-Triclamp		●		●
E	Acid	1/8" × 1/4"	103.0 (2615)	Plug		●	●	●
F	Feed 1	1/4" × 7/16"	53.1 (1350)	Plug		●	●	●
G	Base	1/8" × 1/4"	103.0 (2615)	Plug	●	●	●	●
H	Antifoam	1/8" × 1/4"	103.0 (2615)	Plug	●	●	●	●
I	Feed 2	1/4" × 7/16"	53.1 (1350)	Plug	●	●	●	●
J	Feed 4	1/4" × 7/16"	53.1 (1350)	Plug	●	●	●	●
K	Media	3/8" × 5/8"	53.1 (1350)	Plug	●	●	●	●
L	Inoculum	3/8" × 5/8"	53.1 (1350)	Plug	●	●	●	●
M	Feed 3	3/8" × 5/8"	53.1 (1350)	Plug		●	●	●
N	Sparge 1	1/4" × 3/8"	32.0 (815)	Mini-Triclamp	●	●	●	●
O	Sparge 2	1/4" × 3/8"	32.0 (815)	Mini-Triclamp		●	●	●
P	Sample	1/8" × 1/4"	36.2 (920)	Plug	●	●	●	●
			18.1 (460)	Luer needleless valve		●	●	●
Q	Temperature ²	1/4" × 3/8"	2.6 (65)	Polymeric thermowell	●	●	●	●
R	Perfusion port 1 ⁶	3/4" × 1"	6.1 (155)	ReadyMate™, 3/4"	●	●	●	●
S	Perfusion port 2 ⁶	3/4" × 1"	6.1 (155)	ReadyMate™, 3/4"		●	●	●
T	Sensor port ¹	3/4" × 1/2" reducer	3.4 (86)	AseptiQuik®, 1/2"	●	●	●	●
U	Sensor port ¹	3/4" × 1/2" reducer	3.4 (86)	AseptiQuik®, 1/2"	●	●	●	●
V	Sensor port ¹	3/4" × 1/2" reducer	3.4 (86)	AseptiQuik®, 1/2"	●	●	●	●
W	Sensor port ¹	3/4" × 1/2" reducer	3.4 (86)	AseptiQuik®, 1/2"	●	●	●	●
X	Sensor port ¹	3/4" × 1/2" reducer	3.4 (86)	AseptiQuik®, 1/2"		●	●	●
Y	Sensor port ¹	3/4" × 1/2" reducer	3.4 (86)	AseptiQuik®, 1/2"		●	●	●
Z	Sensor port ¹	3/4" × 1/2" reducer	3.4 (86)	AseptiQuik®, 1/2"		●	●	●
AA	Sensor port ¹	3/4" × 1/2" reducer	3.4 (86)	AseptiQuik®, 1/2"		●	●	●
AB	Harvest	1/2" × 3/4"	48.0 (1220)	ReadyMate™, 1/2"	●	●	●	●
N/A	Exhaust filter 5"	N/A	N/A	ReadyMate™, 1.5" TC	●	●	●	●

¹ Sensor port compatible with Cytiva Click-In Probe Sheath, 12 mm insertion type.

² Compatible with system RTD (Resistance temperature detector), tubing length is internal to bag.

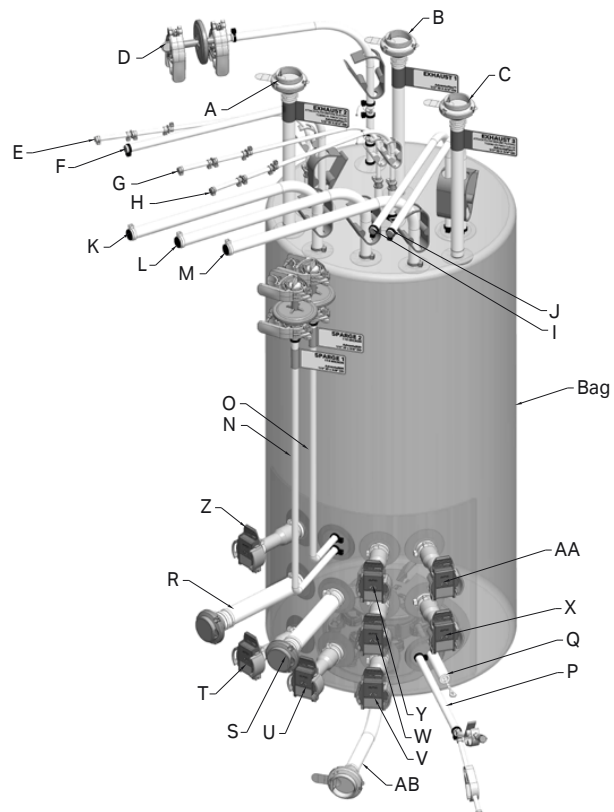
³ Dimensional tolerances according to tubing manufacturer.

⁴ Overall nominal tubing length, excludes fittings.

⁵ Tubing is weldable thermoplastic for bag ports E/F/G/H/I/J/K/L/M/P/AB.

⁶ Perfusion port compatible with tangential flow filtration (TFF) and alternating tangential filtration (ATF).

For more detailed information refer to X-50 Sales drawing 30003437.



Bags for Xcellerex™ X-200 bioreactor

Bag port ⁵	Intended function	Tubing size ³ (ID × OD), inches	Tubing length ⁴ , inches (mm)	Terminal connector	Product code			
					Fed-batch I (29697031)	Fed-batch II (29697030)	Perfusion I (29697028)	Perfusion II (29697027)
A	Exhaust 1	3/4" × 1"	12.6 (320)	ReadyMate™, 3/4"	●	●	●	●
B	Exhaust 2	3/4" × 1"	12.6 (320)	ReadyMate™, 3/4"	●	●	●	●
C	Exhaust 3	3/4" × 1"	12.6 (320)	ReadyMate™, 3/4"	●	●	●	●
D	Overlay	1/4" × 7/16"	26.0 (660)	Mini-Triclamp	●		●	
	Overlay w/ redundant pressure sensor	1/4" × 7/16"	26.0 (660)	Mini-Triclamp		●		●
E	Acid	1/8" × 1/4"	127.0 (3225)	Plug		●	●	●
F	Feed 1	1/4" × 7/16"	84.1 (2135)	Plug		●	●	●
G	Base	1/8" × 1/4"	127.0 (3225)	Plug	●	●	●	●
H	Antifoam	1/8" × 1/4"	127.0 (3225)	Plug	●	●	●	●
I	Feed 2	1/4" × 7/16"	84.1 (2135)	Plug	●	●	●	●
J	Feed 4	1/4" × 7/16"	84.1 (2135)	Plug	●	●	●	●
K	Media	3/8" × 5/8"	84.1 (2135)	Plug	●		●	●
L	Inoculum	3/8" × 5/8"	84.1 (2135)	Plug	●	●	●	●
M	Feed 3	3/8" × 5/8"	84.1 (2135)	Plug	●		●	●
N	Sensor port ¹	3/4" × 1/2" reducer	3.4 (86)	AseptiQuik®, 1/2"				●
O	Sensor port ¹	3/4" × 1/2" reducer	3.4 (86)	AseptiQuik®, 1/2"				●
P	Sparge 1	1/4" × 3/8"	53.1 (1350)	Mini-Triclamp	●	●	●	●
Q	Sparge 2	1/4" × 3/8"	53.1 (1350)	Mini-Triclamp		●	●	●
R	Sensor port ¹	3/4" × 1/2" reducer	3.4 (86)	AseptiQuik®, 1/2"	●	●	●	●
S	Sensor port ¹	3/4" × 1/2" reducer	3.4 (86)	AseptiQuik®, 1/2"	●	●	●	●
T	Perfusion port 1 ⁶	3/4" × 1"	6.1 (155)	ReadyMate™, 3/4"			●	●
U	Perfusion port 1 ⁶	3/4" × 1"	6.1 (155)	ReadyMate™, 3/4"			●	●
V	Sample	1/8" × 1/4"	36.2 (920)	Plug	●	●	●	●
			18.1 (460)	Luer needleless valve				
W	Temperature ²	1/4" × 3/8"	2.6 (65)	Polymeric thermowell	●	●	●	●
X	Sensor port ¹	3/4" × 1/2" reducer	3.4 (86)	AseptiQuik®, 1/2"	●	●	●	●
Y	Sensor port ¹	3/4" × 1/2" reducer	3.4 (86)	AseptiQuik®, 1/2"	●	●	●	●
Z	Sensor port ¹	3/4" × 1/2" reducer	3.4 (86)	AseptiQuik®, 1/2"	●	●	●	●
AA	Sensor port ¹	3/4" × 1/2" reducer	3.4 (86)	AseptiQuik®, 1/2"	●	●	●	●
AB	Harvest	3/4" × 1"	48.0 (1220)	ReadyMate™, 3/4"	●	●	●	●
N/A	Exhaust filter 10"	3/4" × 1"	N/A	ReadyMate™, 1.5" TC		●	●	●
N/A	Exhaust filter 5"	3/4" × 1"	N/A	ReadyMate™, 1.5" TC	●			

¹ Sensor port compatible with Cytiva Click-In Probe Sheath, 12 mm insertion type.

² Compatible with system RTD (Resistance temperature detector), tubing length is internal to bag.

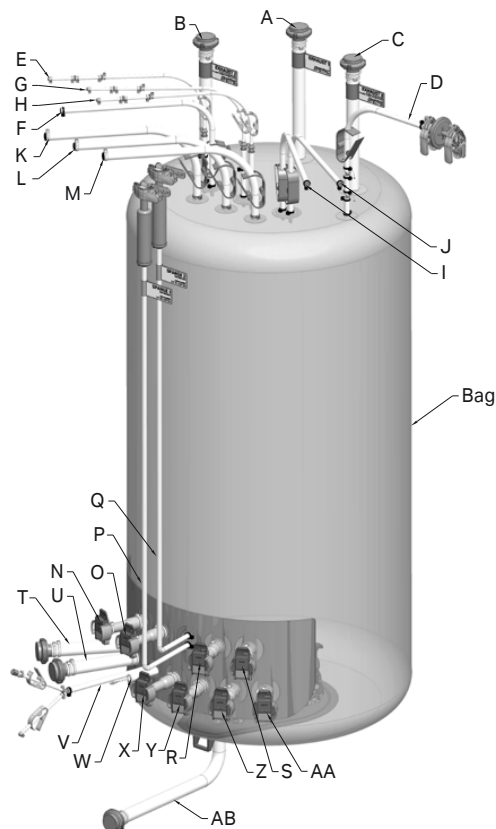
³ Dimensional tolerances according to tubing manufacturer.

⁴ Overall nominal tubing length, excludes fittings.

⁵ Tubing is weldable thermoplastic for bag ports E/F/G/H/I/J/K/L/M/P/AB.

⁶ Perfusion port compatible with tangential flow filtration (TFF) and alternating tangential filtration (ATF).

For more detailed information refer to X-200 Sales drawing 30003438.



Ordering information

To order or learn more about Xcellerex™ *X-platform* bioreactors, please contact your local sales representative.

cytiva.com/xcellerex

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

Cytiva and the Drop logo are trademarks of Life Sciences IP Holdings Corp. or an affiliate doing business as Cytiva. Figurate, OptiRun, ReadyKleer, ReadyMate, and Xcellerex are trademarks of Global Life Sciences Solutions USA LLC or an affiliate doing business as Cytiva.

AseptiQuik is a trademark of Colder Products Company and a registered trademark of the U.S. Patent & Trademark Office. ControlLogix, FactoryTalk, and PlantPAx are trademarks of Rockwell Automation Inc. Watson-Marlow is a trademark of Watson Marlow Pumps Limited. Modbus is a trademark of Schneider Electric USA, Inc. Any other third-party trademarks are the property of their respective owners.

© 2023 Cytiva

CY30031-18Apr23-DF

