Start-Up Checklist: Xpansion® Bioreactor with mPath™ Control Tower (US)

Xpansion Bioreactor Start-Up Checklist Section A: Installation

Purpose

This document details a list of items needed for bioreactor installation. Please complete using the following convention:

☑	If an item is already in the possession of the customer, mark the box with a 'check' mark
☐	If an item is required, but either on order, or needs to be ordered (not currently in the customer's possession), then circle the box and follow up after
☒	If an item is not required for this project, place an 'x' over the box
☑	Once an ordered item has been received and properly staged by the customer, mark the box with a 'check' mark

Project Information

Please record information pertaining to who reviewed the start-up checklist and when the review was performed:

Pall Customer Company Name: _____

Pall Customer Contact Individual: _____

Pall Field Service Engineer: _____

Date First Reviewed (kick off call): _____

Date of Next Meeting: _____

Meeting Summary and Action Items:

Readiness Confirmation:

The Pall Service Engineer will not come onsite to perform the bioreactor installation until the customer has signed, confirming that all necessary items have been obtained and are properly staged.

_____ _____

Signature of Customer Date

Start-Up Checklist: Xpansion® Bioreactor with mPath™ Control Tower (US)

Section A: Installation

Basic Hardware

	Description	Vendor	Part Number	Comments
☐	Xpansion bioreactor system	Pall	XPNBRS	Includes: mPath control tower, docking station, magnetic stir plate, 2 fiber optic cables (1 pH, 1 dissolved oxygen [DO]), PT100 temp probe, and 110 V power cable
	mPath control tower[1]	Pall	KMPATHBRXPS2P0	Configured for Xpansion bioreactor (contains PreSens♦ transmitter, no pumps)
	Fiber optic cables[1]	Pall	XPNPHCBLE	3 m cables to support PreSens single-use sensors
☐	Stir plate extension cable[2]	Variomag	MF46200	Extension cable for the magnetic stir plate (needed if control is a far distance from incubator) Distributed in the US by 2-Mag-USA: https://www.2magusa.com/2mag-biomixdrive-extension-cable.html
☐	Harvest station	Pall	XPNHVST	Mechanical cell detachment device for harvest
☐	Pall Link server and SCADA	Pall	MPATHLINK	Contains server, software, and cables to interact with control tower
☐	Monitor	Various	User specified	Monitor requires HDMI connectivity and an HDMI cable
☐	Keyboard/mouse	Various	User specified	Any mouse/keyboard combination with USB connectivity will suffice (wired preferred)
☐	Ethernet router/switch[2]	Staples	IM11Y1022	For wired networks: CAT6, TP-LINK TL-SG108-KIT, 8-Port, 10/100/1000 Mbps
			IM1DW2680	For a local wireless network: CAT6, TP-Link TL-WR841N, 300 Mbps
☐	Lift[2]	Pall	XPNLIFT	Required to move the XPN100 and XPN200
☐	Pall tool kit[2]	Pall	CCTOOLKIT1	Assists in mPath gas installation: 6 mm pneumatic tubing, hand pump, 6 mm push-to-connect ‘Y’, 6 mm push-to-connect x ¼ in. barb adaptor, 6 mm x 6 mm push-to-connect straight adaptor

[1] Denotes an item include in the Xpansion control system

[2] Denotes optional item, although the Dino-Lite♦ microscope is highly recommended for new Xpansion bioreactor users.

Lab Equipment

	Description	Vendor	Part Number	Comments
☐	Battery backup (UPS)	APC	*TBD*	Use calculator to determine VA requirement: http://www.apc.com/us/en/tools/ups_selector/server/load Power requirement = 360 W
		Grainger	4HHH6	10-60 min, 750 VA (375 VA required)
☐	Incubator	*Many available*		37 °C for reagent warming and flatware control culture. Also used to house bioreactor and docking station. Check dimensions. Ensure incubator contains 2 in. hole to pass cables
		Shelco	*Model 2440*	Incubator with reinforced shelving for heavier bioreactors. Required for the XP100 and XP200

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Section A: Installation

Gas Supply

Description	Vendor	Part Number	Comments
☐ Oxygen tank	Airgas	OX USP200	200 cubic feet, medical grade, dry
☐ Air tank	Airgas	AI USP200	200 cubic feet, medical grade, dry
☐ CO_2 tank	Airgas	CD USP50	50 lbs, medical grade, dry
☐ Nitrogen tank[2]	Airgas	NI 300	200 cubic feet, medical grade, dry
☐ Oxygen regulator	Airgas	Y12244D540	2-6 bar (29-87) psi; contains ¼ in. NPT connection, CGA540
☐ Air regulator	Airgas	Y12244D346	2-6 bar (29-87) psi; contains ¼ in. NPT connection, CGA346
☐ CO_2 regulator	Airgas	Y12244D320	2-6 bar (29-87) psi; contains ¼ in. NPT connection, CGA320
☐ Nitrogen regulator[2]	Airgas	Y12244D580	2-6 bar (29-87) psi; contains ¼ in. NPT connection, CGA580
☐ Push-to-connect adaptors	McMaster Carr	5225K713	¼ in. threaded male to 6 mm
		50785K92	¼ in. threaded female straight adaptor
		5225K87	6 mm 'Y' splitter; required for multiple control towers
☐ Pneumatic tubing	McMaster Carr	5195T52	Color: clear; 6 mm diameter; sold in 25 ft. quantities; Other colors also available

[2]Denotes an optional item

Ensure enough pneumatic tubing is order to span the distance between gas tank and controller.

Miscellaneous

Description	Comments
☐ Bench space requirement	50 cm x 100 cm is required for bioreactor operations (filling/draining). 60 cm x 80 cm is required footprint for controller and HMI
☐ Incubator space requirement	XPN10- 49 cm x 48 cm x 40 cm XPN50- 67 cm x 48 cm x 40 cm XPN100- 75 cm x 48 cm x 40 cm XPN200- 99 cm x 48 cm x 40 cm
☐ Floor space requirement	Lift- 70 cm x 152 cm x 200 cm Free space on floor in front of microscope and incubator to operate lift = 80 cm x 160 cm (more preferred)
☐ Installation Verification/ Operational Verification (IVOV) documents[2]	An IVOV can be ordered as an optional service to augment bioreactor installation. If the IVOV services is ordered, a copy of the protocol should be obtained and approved in advance of the installation. IVOV Service part number: A10165 IVOV document part number: XPNBRSIVOV (both parts are required)
☐ Control tower networking	The mPath control tower(s) can either be installed on an isolated network or a larger area network. Please select the customer preference: ☐ Isolated network ☐ Local area network If a local area network was chosen, please confirm the following: ☐ The customer has read and understood the IT Tech Note ☐ IP address has been obtained: _____ ☐ Subnet mask has been obtained: _____ ☐ Preferred DNS server has been obtained: _____

[2] Denotes an optional item

Start-Up Checklist: Xpansion® Bioreactor with mPath™ Control Tower (US)

Xpansion Bioreactor Start-Up Checklist Section B: Operation

Purpose

This document details a list of items needed for bioreactor training. Please complete using the following convention:

☑	If an item is already in the possession of the customer, mark the box with a 'check' mark
☐	If an item is required, but either on order, or needs to be ordered (not currently in the customer's possession), then circle the box and follow up after
☒	If an item is not required for this project, place an 'x' over the box
☑	Once an ordered item has been received and properly staged by the customer, mark the box with a 'check' mark

Project Information

Please record information pertaining to who reviewed the start-up checklist and when the review was performed:

Pall Customer Company Name: _____

Pall Customer Contact Individual: _____

Pall Bioreactor Application Scientist: _____

Date First Reviewed (kick off call): _____

Date of Next Meeting: _____

Meeting Summary and Action Items:

Readiness Confirmation:

The Pall Bioreactor Application Scientist will not come onsite to perform the bioreactor training until the customer has signed, confirming that all necessary items have been obtained and are properly staged.

_____ _____

Signature of Customer Date

Start-Up Checklist: Xpansion® Bioreactor with mPath™ Control Tower (US)

Section B: Operation

Vessels

Description	Vendor	Part Number	Comments
☐ XPN10	Pall	XPN10	6,120 cm^2
☐ XPN50	Pall	XPN50	30,600 cm^2
☐ XPN100	Pall	XPN100	61,200 cm^2
☐ XPN200	Pall	XPN200	122,400 cm^2

Most Xpansion bioreactor trials will require the preordering of at least three XPN10 systems.
All Xpansion consumables have PreSens sensors. The two liquid addition lines are ⅜ in. internal diameter (ID) x ⅝ in. outer diameter (OD) weldable, male MPC connector.

Manifolds

Description	Vendor	Part Number	Comments
☐ XPN10 seeding manifold	Pall	6100097S	2 L Nalgene• bottle; ¼ in. ID x 7/16 in. OD (L/S size 24) silicone; female MPC; used to transfer material to and from XPN10
☐ Pooling manifold[2]	Pall	6100129	Identical to 2 L seeding manifold but with 10 L bottle; used to seed an XPN50 or transfer material to and from larger biocontainer seeding manifolds
☐ XPN50 seeding manifold	Pall	5190-1099C	Standard 10 L Allegro 2D biocontainer. 3 tubing lines: • 12 in. ¼ in. ID x 7/16 in. OD, weldable, female luer • 24 in. ⅜ in. ID x ⅝ in. OD, weldable, male MPC • 24 in. ⅜ in. ID x ⅝ in. OD, weldable, female MPC
☐ XPN100 seeding manifold	Pall	5190-1099B	Standard 20 L Allegro 2D biocontainer. 3 tubing lines: • 12 in. ¼ in. ID x 7/16 in. OD, weldable, female luer • 24 in. ⅜ in. ID x ⅝ in. OD, weldable, male MPC • 24 in. ⅜ in. ID x ⅝ in. OD, weldable, female MPC
☐ XPN200 seeding manifold	Pall	5190-1060Z	Standard 50 L Allegro 2D biocontainer. 3 tubing lines: • 12 in. ¼ in. ID x 7/16 in. OD, weldable, female luer • 24 in. ⅜ in. ID x ⅝ in. OD, weldable, male MPC • 24 in. ⅜ in. ID x ⅝ in. OD, weldable, female MPC

[2]Denotes optional item
Manifolds can also be built and customized by customers. Contact applications support for build sheets.

Lab Consumables

Description	Vendor	Part Number	Comments
☐ Luer lock cap	Cole Parmer	45502-28	Female luer thread style cap
☐ Luer lock syringe	VWR	BD309604	10 mL, for bioreactor sampling
		BD309653	60 mL, for foam trap assembly filling; ensure media container opening is wide enough to fit syringe

Start-Up Checklist: Xpansion® Bioreactor with mPath™ Control Tower (US)

Section B: Operation

Tube Welding[2]

	Description	Vendor	Part Number	Comments
☐	Tubing welder[2]	Sartorius	16389	
☐	Welder holder/jaws[2]	Sartorius	16389-001	For ⅜ in. ID x ⅝ in. OD C-Flex♦ tubing
☐	Welder blades[2]	Sartorius	16389-012	Disposable cutting blades for tubing, Box of 50
☐	Tubing sealer[2]	Sartorius	16362-P8	Aseptically seals tubing for disconnections; ½ in. to ¾ in. OD

[2]Denotes optional item

Tubing connection can be made aseptically via welding if all tubing is C-Flex; otherwise connections are made aseptically in biosafety cabinet using MPC quick connects.

Fluid Handling

	Description	Vendor	Part Number	Comments
☐	Balance/scale[2]	VWR	89203-158	Used for measuring media volumes; 5 kg capacity
☐	Hand pump	Pall	ICLNHPMPPVCRUBBLK	AKA pressure bulb, used to pressure transfer fluid from one vessel to another
☐	Peristaltic pump drive[2]	Cole-Parmer	EW-07522-20	High speed 6 - 600 rpm drive, 0 – 8 mm (0 – 5/16 in.) ID L/S tubing, analog input capable
			EW-77420-10	High speed 20 - 650 rpm drive, 6 – 16 mm (¼ in. – ⅝ in.) ID I/P tubing, analog input capable
☐	Peristaltic pump head[2]	Cole-Parmer	GJ-77800-60	1/16 in. – ⅜ in. ID, 1/16 in. (1.6 mm) wall thickness (L/S size 13, 14, 16, 17, 18, 25)
			GJ-77800-62	3/16 in. – ⅜ in. ID, 3/32 in. (2.4 mm) wall thickness (L/S size 15, 24, 35, 36)
			EW-77602-10	¼ in. - ½ in. ID, ⅛ in. (3.2 mm) wall thickness (I/P size 26, 73, 82)

[2]Denotes optional item

Fluid transfer can be accomplished either with a hand pump or peristaltic pump. If using a peristaltic pump, choose either an I/P or L/S style pump and pump head. Consult your application specialist for recommendations. Tubing connection can be made aseptically via welding if all tubing is C-Flex; otherwise connections are made aseptically in biosafety cabinet using MPC quick connects.

Lab Reagents

	Description	Vendor	Part Number	Comments
☐	Glycerol	VWR	200012-594	Contact gel for thermo well
☐	Trypan blue	VWR	95037-580	Used for viable cell counting
☐	Isopropanol	*Many available*		Sanitizing agent
☐	PBS	*Many available*		Used for cell rinsing during harvest
☐	Diluted protease solution	*Process dependent*		i.e. Trypsin or TrypLE♦; concentration determined via T-Flask screening experiments
☐	pH Buffer	VWR	BDH5046	pH 7.0
		VWR	BDH5018	pH 4.0

Start-Up Checklist: Xpansion® Bioreactor with mPath™ Control Tower (US)

Section B: Operation

Offline Sampling and Analytics

Description	Vendor	Part Number	Comments
☐ Metabolite analyzer[2]	Beckman-Coulter	MetaFlex	Contact Beckman-Coulter for a free demo: http://info.beckmancoulter.com/Metaflex-info Measures: pH, pCO_2, pO_2, glucose, lactate, Na, K, Cl
☐ Glucose meter	CVS/ Walgreens	N/A	Accu-Chek Guide♦ - Verified to measure cell culture media
☐ Glucose meter strips	CVS/ Walgreens	N/A	Ensure compatibility with Accu-Chek Guide meter
☐ Lactate meter	Fisher	NC0214475	
☐ Lactate meter strips	Fisher	NC0215913	Single use consumable for lactate meter
☐ pH probe	VWR	BKA57180	Used to verify and recalibrate online pH probe
☐ Thermometer[2]	VWR	23226-658	
☐ Dino-Lite digital microscope[2]	Dinolite US	AF4515ZTL	140X magnification http://www.dinolite.us/af4515ztl
☐ Dino-Lite stand[2]	Dinolite US	RK-06A	Allows easy, smooth, fine vertical adjustment of the microscope
☐ Hemocytometer	VWR	15170-172	Used to count cells
☐ Click counter	VWR	10200-146	Used to count cells
☐ Microscope	*Many available*		Used to count cells

[2]Denotes an optional item

In place of hemocytometers, an automated cell counting instrument can be used. The Pall application team recommends daily glucose and lactate measurements at a minimum

Manifold Parts[2]

Description	Vendor	Part Number	Comments
☐ Bottles[2]	BioFluid Focus	202000-05	2 L; Can be used to build 2 L seeding manifolds (XPN10)
		210000-01	10 L; Can be used to build 10 L seeding manifolds (XPN50)
		220000-01	20 L; Can be used to build 20 L seeding manifolds (XPN100)
☐ Ported caps[2]	BioFluid Focus	4048CP3-50	48 mm; For 2 L bottles and smaller
		4070CP2-50	70 mm, For 5 L bottles and larger
☐ Tubing	Cole-Parmer	EW-96410-25	$^3/_{16}$ in. ID x $^5/_{16}$ in. OD (L/S size 25), silicone
		GJ-96410-15	$^3/_{16}$ in. ID x $^7/_{16}$ in. OD (L/S size 15), silicone
		GJ-06424-73	⅜ in. ID x ⅝ in. OD (I/P size 73), weldable
☐ MPC quick connect	Cole-Parmer	EW-31311-71	Insert (male), ¼ in. barb
		EW-31311-21	Body (female), ¼ in. barb
☐ Vent filter	VWR	28143-514	Acro® 37 filter, 0.2 µm
☐ Tubing clamps[2]	VWR	63022-405	

[2]Denotes an optional item

Items above many be used to build custom manifolds. Custom manifolds will be required for XPN50 scale and larger. Contact application support for build sheets. Mandatory items above are needed to build an exhaust heater manifold.

Start-Up Checklist: Xpansion® Bioreactor with mPath™ Control Tower (US)

Section B: Operation

Lab Equipment

Description	Vendor	Part Number	Comments
☐ Biosafety cabinet	*Many available*		Used for all aseptic operations
☐ Autoclave	*Many available*		For autoclaving custom manifolds
☐ Water bath	*Many available*		37 °C for reagent warming
☐ Cell processor	Fresenius Kabi	Lovo	Automated instrument to concentrate cells post-harvest Contact page for free demo: http://chooselovo.com/
☐ Incubator temperature monitoring	*Many available*		Use a calibrated digital thermometer to ensure the interior of the incubator can be stably maintained at the desired process set point

Biologic Materials

Description	Comments
☐ Xpansion bioreactor prep experiments	• In the current cell culture format (i.e. T-Flask), sample daily to measure pH. If possible, also measure other media chemistries such as DO, glucose, lactate, etc. These measurements will help inform the decision of pH and DO set points for the first Xpansion bioreactor experiment. • Perform the set of experiments detailed in the 'Xpansion Harvest Condition Screening in T-Flasks' protocol to optimize the harvest conditions tested in the first Xpansion bioreactor experiment
☐ Cell culture media volume requirements	Same media formulation as most current process. Vessel volumes: XPN10- 1.7 L XPN50- 5.8 L XPN100- 12.0 L XPN200- 22.5 L Equal volumes of PBS and protease solution will also be required for harvesting cells. More volume will be required if performing media exchanges
☐ Cell feed stock	Provide a sufficient number of cells to maintain the same cell seeding density as current process. Must take into account non-contact volume by multiplying with the following correction factors. Also provide sufficient cells to seed a control flask. XPN10- 1.73 XPN50- 1.04 XPN100- 1.04 XPN200- 1.03 For example: • Current process utilizes a cell seeding density of 3,000 cells/cm^2 In the XPN10, this results a total cell requirement of 31.7 million cells (3,000 cells/cm^2 x 6120 cm^2 x 1.73)

USD 3362

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