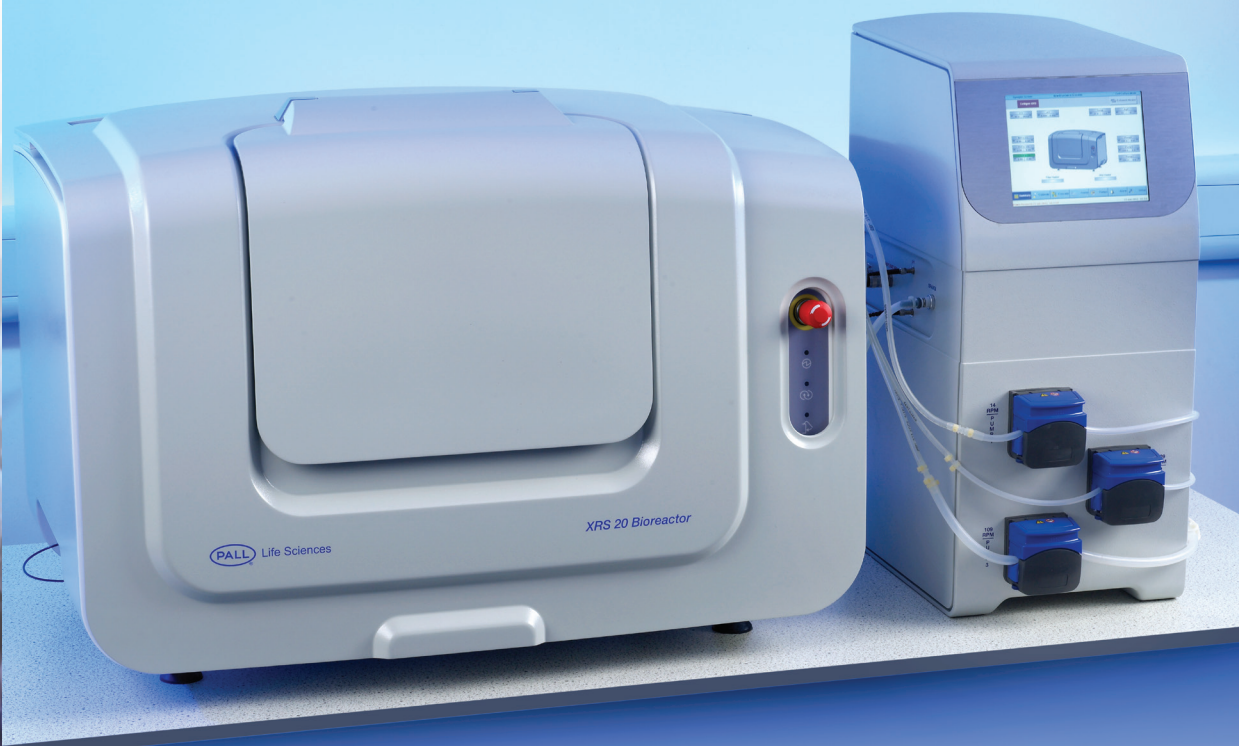




Life Sciences

USD 2873

## XRS 20 Bioreactor System



### *Unique agitation improves cell culture performance*

The XRS 20 Bioreactor System is a new single-use bioreactor system with unique agitation and control properties designed for the cultivation of mammalian cells in suspension culture under controlled conditions and suitable for applications ranging from general life sciences research to seed train operations and full GMP production at the 2 to 20 liter scale.

Comprised of three components (XRS 20 Platform, XRS 20 Controller, and Allegro™ XRS 20 Biocontainers), the XRS System produces superior performance (as measured by higher density, better cell viability, and higher expression levels) compared to competitor rocker systems because its unique Bi-Axial agitation produces shorter mixing times and higher mass transfer properties.



*Pall XRS 20 Platform with installed Allegro XRS 20 Biocontainer*

***Filtration. Separation. Solution.<sup>SM</sup>***

## Bi-Axial Rocker for Better Mixing and Mass Transfer

The XRS bioreactor system rocks on two axes simultaneously (Bi-Axial agitation), producing a low turbulence, swirling pattern within the 3-dimensional XRS 20 Biocontainer. Under similar agitation conditions, the XRS system mixes almost 3 times faster than conventional rockers, and demonstrates much higher mass transfer properties as measured by  $k_L a$  values.

Summary of best mixing times observed in pH equilibration studies, 20 liter working volumes with conventional pH probes<sup>1</sup>

System	Condition	Mixing Time (s)
Conventional	Maximum speed and rock angle = 42 rpm, 10.4°	50 to 98 seconds <sup>3</sup>
XRS 20	75% Max speed, maximum long axis angle, 1/3 short axis angle = 30 rpm, 15° long, 5° short	16 seconds

Summary of mass transfer coefficients observed in 20 liter working volumes as measured with nitrogen purge and recovery<sup>2</sup>

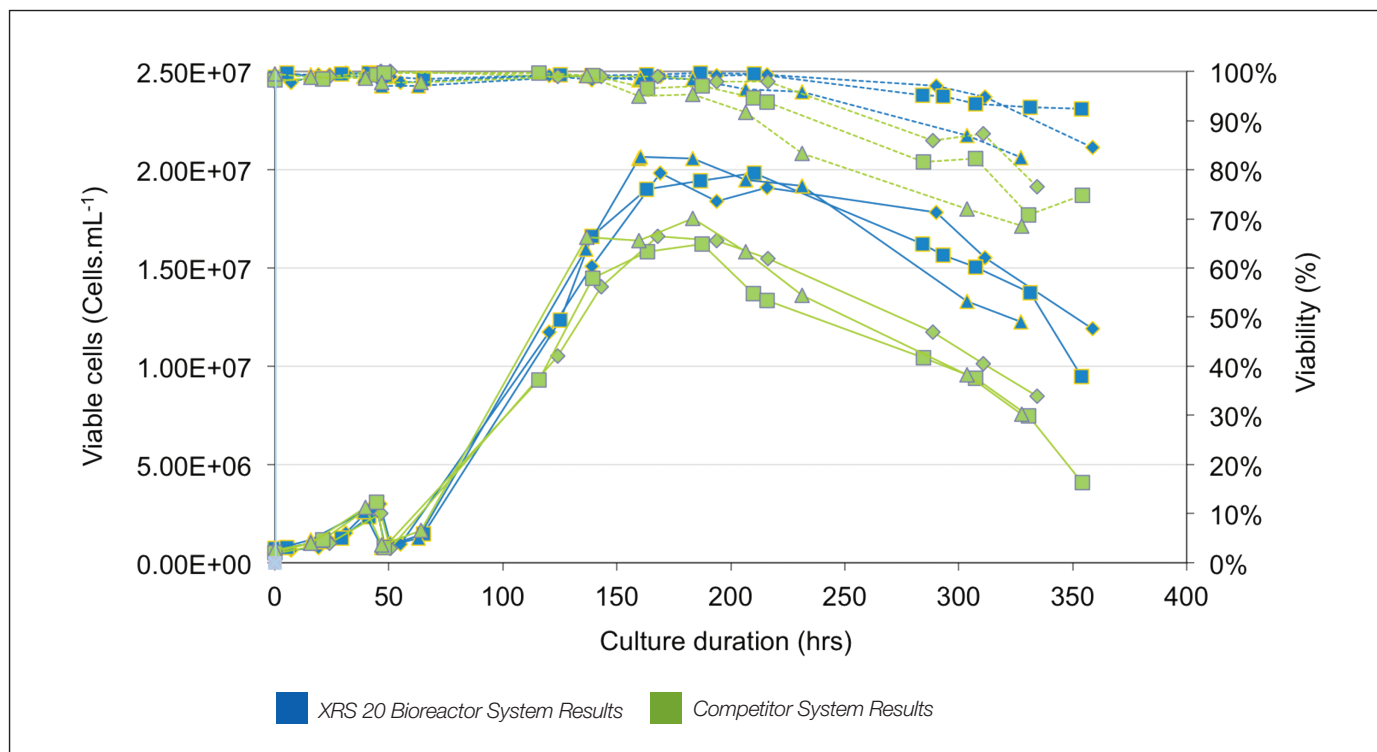
System	Condition	KLa per Hour
Conventional	Maximum speed and rock angle = 42 rpm, 10.4°	42
XRS 20	Maximum speed and angle = 40 rpm, 15° long, 15° short	73

<sup>1</sup> Mixing trial results from 3 repetitions for each device <sup>2</sup> Mass transfer results from 3 repetitions for each device <sup>3</sup> Times significantly different for edge/center measurements  
For additional details on mixing and mass transfer studies, contact [bioreactors@pall.com](mailto:bioreactors@pall.com)

## Better Mixing, Better Cell Culture Performance

The superior mixing properties due to the design of the 3-D biocontainer and the bi-axial agitation leads to superior cell culture performance in mammalian suspension systems. With faster delivery of nutrients to the cellular micro-environment (and faster removal of metabolites), the XRS 20 System allows cells to attain higher densities, and with higher overall viabilities, leading to much significantly higher protein expression levels. In the batch culture example cited below, with identical media inputs and seeds, the Pall XRS Bioreactor System produced 18% higher cell densities, and 30% more antibody titer compared to conventional rocker technologies.

Summary of side-by-side growth and viability experiments (n=3) at 20 liter working volumes comparing conventional rocker system and Pall XRS 20 system. Simple batch culture of a CHO (Chinese hamster ovary) cell line expressing a monoclonal antibody.



For full experimental details, see your local Pall representative or contact [bioreactors@pall.com](mailto:bioreactors@pall.com)

The XRS 20 Bioreactor System incorporates a number of other features to ensure easy operation, robust performance, and suitability for GMP operations:

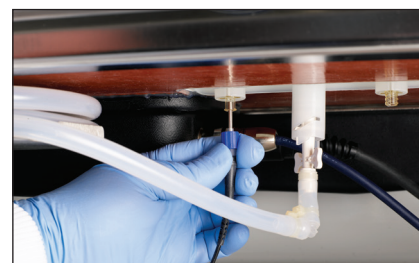
Feature	Benefits
<b>XRS 20 Platform</b>	
Bi-axial agitation (rocking motion on two horizontal axes at 90 degrees separation)	Improved agitation properties: shorter mixing times and higher mass transfer rates
Fully enclosed platform with safety interlock	Improved operator safety, suitable for production environments, protects light sensitive culture media
<b>Allegro XRS 20 Biocontainer</b>	
3 dimensional biocontainer design	Superior mixing (with bi-axial platform), robust in operation
Biocontainer with integrated optical sensors, integrated filters, pre-assembled tubing sets	True single use system, ease of installation, minimal turn-around time
Gas inlet and exhaust filters are integrity testable, sterilizing grade 0.2 µm	Improved suitability for GMP operations
Integrated bottom drain with rotary lift valve	Improved suitability for GMP operations, minimal hold up volume, ease of use
Multiple liquid addition ports: Main liquid addition line with female CPC Reagent line 1 with female luer Reagent line 2 with female luer Accessory port with female luer	Improved ease of use, easily handles fed batch operations, acid/base pH control feeds
Integrated single use pH and Dissolved Oxygen (DO) sensors	Ease of use and reduced probability of contamination
Integrated sampling port	Ease of use - Very low hold up volume (less than 5 mL), capable of sampling without stopping agitation
Single-use biocontainer built with Allegro film	Assurance of robustness, quality and supply, track record of use of film in GMP operations, validation guide available
<b>XRS 20 Controller</b>	
Advanced, full function, small footprint controller with touchscreen interface	Easy to use, but with powerful control capabilities (below). Touchscreen simplifies setup, calibration, operation, alarms, trending and process data collection
3 thermal mass flow gas controllers	Accurate 3 gas mixing and flow control, programmable
Full function control software	Powers intuitive graphical displays, including synoptic view, summary screen, trend graphing Enables automatic process control of agitation, temperature, pH, DO, gas flow and mixture Allows on-screen calibration for sensors and pumps Supports user definable P&I settings for fine tuning of process control loops Customizable alarms for process monitoring Customizable loop trending for up to 8 variables, simultaneously Stores up to 10 user-definable recipes Assigns peristaltic process pumps for additions and harvest CFR21 Part 11 compatible. Multilevel security to limit setpoint control access
Integrated USB ports	Rapid, easy data collection and software updates
Convenient access to utility connections	Quick set up and easy maintenance
In-line container pressure monitor with relief valve	System robustness – prevents over pressuring of biocontainer



*Tubing management system*



*In-process sampling*



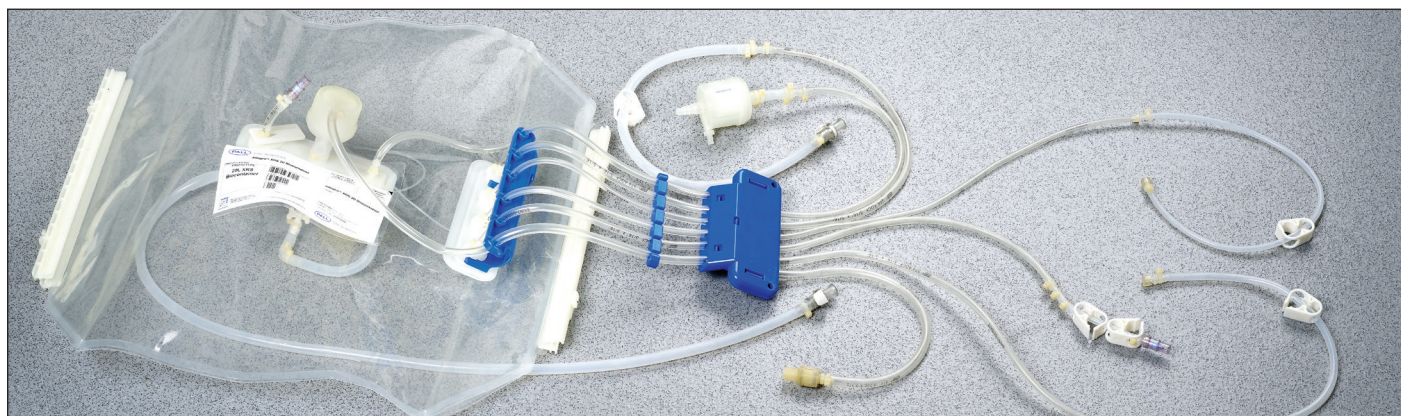
*Drain and optical sensors*

## Specifications

### XRS 20 Bioreactor System Specifications

Allegro XRS 20 Biocontainer	Minimum Working Volume	2 L
	Maximum Working Volume	20 L
	Irradiated	Gamma: dose 25-40 Kgray
Controller	Control Station	Controls up to 32 control loops; stores 10 recipes and 8 process variables for trend graphing. Includes an industrial touchscreen monitor/user interface, 3 built-in pumps & connectors for all utilities & communications signals.
	Touchscreen Interface/Display	25.4 cm (10 in) LED monitor
Temperature	Indication	Digital display in 0.1 °C increments
	Range	From 8 °C above ambient temperature to 40 °C (ambient temperature defined as 10 to 30 °C)
	Control	P&I control for heating. Heating is assured via the heater mat and cooling via ambient temperature.
	Sensor	Platinum RTD probe
Agitation	Drive	Stepper motors
	Indication	Digital display in 1 rpm increments.
	Range	1 - 35 rpm
	Angle	-15° to +15° in both X and Y directions
	Control	Stepper motor controlled
Exhaust	Filter	0.2 µm disposable filter (integrated with biocontainer)
	Exhaust Heater	Silicone heater mat
Aeration	3-Gas System	Up to 3 gases (Air, O <sub>2</sub> , CO <sub>2</sub> , or Mixture), Thermal Mass Flow Control
	Sparger	Gas sparged into biocontainer headspace
	Inlet Filter	0.2µm disposable filter (integrated with biocontainer)
pH	Indication	Digital display in 0.01 pH increments
	Range	6 - 8 pH
	Control	P&I
	Sensor	Non-invasive optical pH probe
DO	Indication	Digital display in 0.1% increments
	Range	0 - 200%
	Control	3-gas P&I control
	Sensor	Non-invasive optical DO probe
Pumps	Pump 1	Assignable peristaltic pump Fixed speed (14 rpm) or variable duty cycle Available control modes: Off, On, Prime.
	Pumps 2 & 3	Assignable peristaltic pumps Fixed speed (109 rpm) or variable duty cycle Available control modes: Off, On, Prime.
Utilities	Gas	68.9 mbar (1 PSIG) maximum
Electrical Requirements	Control Station	100-240 VAC, 50/60 Hertz, Single phase, 13 amp
	Reactor Platform	105-230 VAC, 50-60 Hertz, Single phase, 13 amp
Power Rating, Reactor Platform		1150 W
Net Weight	Control Station	20 kg (44 lb)
	Reactor Platform	78 kg (171.6 lb)
Overall Dimensions XRS Control Cabinet		29.5 cm W X 40.6 cm D X 66.8 cm H (11.6 in. wide X 16 in. deep X 26.3 in. high)

Overall Dimensions Reactor Platform	90 cm W X 60 cm D X 62 cm H (35.4 in. wide X 23.6 in. deep X 23.6 in. high) ① Allow for the lid's 20cm overhang at the rear of the platform, and factor in an additional 37 cm to the overall height when the lids are open.
External Computer Connections	Ethernet port supplied for future connection to supervisory host computer
Fuses	2 Cooper Bussmann S505-10-R 5 x 20 mm 10 A fuses
Regulatory Compliance	See Section 5.1 Instructions For Use USD 2875
Ambient Operating Conditions	10 – 40 °C, up to 80% relative humidity, non-condensing



*Allegro XRS 20 biocontainer supplied as a complete, ready-to-use, single-use system*

## **Allegro XRS 20 Biocontainer Tubing & Connection Specifications**

<b>Use</b>	<b>Tubing Type</b>	<b>Length</b>	<b>Size</b>	<b>Connection</b>
Spare addition port	Thermo-elastomer	50 mm (2 in.)	4.8 mm ID x 7.9 mm OD ( $\frac{3}{16}$ in. ID x $\frac{5}{16}$ in. OD)	Swabable female luer
Gas inlet tube	Thermo-elastomer	858 mm (34 in.)	4.8 mm ID x 7.9 mm OD ( $\frac{3}{16}$ in. ID x $\frac{5}{16}$ in. OD)	0.2 $\mu$ m filter with tapered hose tail
	Platinum Cured Silicone	50 mm (2 in.)	6.35 mm ID x 11.11 mm OD ( $\frac{1}{4}$ in. ID x $\frac{7}{16}$ in. OD)	
Main liquid addition tube	Thermo-elastomer	800 mm (32 in.)	3.18 mm ID x 6.4 mm OD ( $\frac{1}{8}$ in. ID x $\frac{1}{4}$ in. OD)	6.35 mm ( $\frac{1}{4}$ in.) MPC
	Platinum Cured Silicone	500 mm (20 in.)	6.35 mm ID x 11.11 mm OD ( $\frac{1}{4}$ in. ID x $\frac{7}{16}$ in. OD)	
Addition tube 2	Thermo-elastomer	800 mm (32 in.)	3.18 mm ID x 6.4 mm OD ( $\frac{1}{8}$ in. ID x $\frac{1}{4}$ in. OD)	Female luer
	Platinum Cured Silicone	500 mm (20 in.)	3.18 mm ID x 6.4 mm OD ( $\frac{1}{8}$ in. ID x $\frac{1}{4}$ in. OD)	
Sampling tube	Thermo-elastomer	685 mm (27 in.)	4.8 mm ID x 7.9 mm OD ( $\frac{3}{16}$ in. ID x $\frac{5}{16}$ in. OD)	Swabable female luer
	Platinum Cured Silicone	100 mm (4 in.)	3.18 mm ID x 6.4 mm OD ( $\frac{1}{8}$ in. ID x $\frac{1}{4}$ in. OD)	
Addition tube 1	Thermo-elastomer	800 mm (32 in.)	4.8 mm ID x 7.9 mm OD ( $\frac{3}{16}$ in. ID x $\frac{5}{16}$ in. OD)	Female luer
	Platinum Cured Silicone	500 mm (20 in.)	4.8 mm ID x 7.9 mm OD ( $\frac{3}{16}$ in. ID x $\frac{5}{16}$ in. OD)	
Gas vent tube	Thermo-elastomer	913 mm (36 in.)	6.35 mm ID x 11.11 mm OD ( $\frac{1}{4}$ in. ID x $\frac{7}{16}$ in. OD)	0.2 $\mu$ m filter with downstream check valve with 1.3 mm ( $\frac{1}{2}$ in.) hose tail
Drain tube	Platinum Cured Silicone	1283 mm (50.5 in.)	6.35 mm ID x 11.11 mm OD ( $\frac{1}{4}$ in. ID x $\frac{7}{16}$ in. OD)	6.35 mm ( $\frac{1}{4}$ in.) MPC

## Ordering Information

Description	Part Number
XRS 20 Bioreactor System	XRS20BR
XRS 20 Bioreactor System Validation Package IQ/OQ Documentation Package	XRS20IQOQ
XRS 20 Bioreactor System Installation Kit	XRS20REGTREE
Allegro XRS 20 Biocontainer (with User-Fit pH Sensor Probe) Pack of 4 each	609-40A
<b>Allegro XRS 20 Biocontainer Accessories</b>	
20 Liter, 2D Biocontainer bag with integrated sterilizing filter, Male CPC Connector, gamma irradiated	509-2297
5 Liter, 2D Biocontainer with integrated sterilizing filter, Male Luer Connector, gamma irradiated	509-2296
1 Liter, 2D Biocontainer with integrated sterilizing filter, Male Luer Connector, gamma irradiated	509-2295
500 mL, 2D Biocontainer with integrated sterilizing filter, Male Luer Connector, gamma irradiated	509-2294
"Y" linker, with 2 Female Luer Connections, 1 Male Luer Connector, gamma irradiated	509-0283
Spare Fiber Optic Cables	XRS20FOCAB



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### Corporate Headquarters

Port Washington, NY, USA  
+1.800.717.7255 toll free (USA)  
+1.516.484.5400 phone  
biopharm@pall.com e-mail

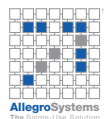
### European Headquarters

Fribourg, Switzerland  
+41 (0)26 350 53 00 phone  
LifeSciences.EU@pall.com e-mail

### Asia-Pacific Headquarters

Singapore  
+65 6389 6500 phone  
sgcustomerservice@pall.com e-mail

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Visit us on the Web at [www.pall.com/allegro](http://www.pall.com/allegro)

E-mail us at [bioreactors@pall.com](mailto:bioreactors@pall.com)

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