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BIOTECH

Allegro™ XRS 25 Bioreactor System

USD3237a

Unique Bi-Axial Agitation Improves Cell Culture Performance

The Allegro XRS 25 bioreactor system is a single-use bioreactor system with unique agitation and control properties designed for the cultivation of mammalian cells in suspension culture under controlled conditions. It is suitable for applications ranging from general life sciences research to seed train operations and full consumer good manufacture practices (cGMP) production at the 2 L to 25 L scale.

Because of its unique bi-axial agitation and the subsequent shorter mixing times and higher mass transfer properties, the Allegro XRS 25 bioreactor system produces superior performance compared to competitor rocker systems, as measured by higher density, better cell viability, and higher expression levels.

The Allegro XRS 25 bioreactor system rocks on two axes simultaneously (bi-axial agitation), producing a low turbulence, swirling pattern within the 3D Allegro XRS 25 biocontainer bag. Under similar agitation conditions, the Allegro XRS 25 bioreactor system mixes almost 3 times faster than conventional rockers (Table 1), and demonstrates much higher mass transfer properties as measured by k_La values (Table 2).

Table 1

Summary of best mixing times observed in pH equilibration studies, 20 L working volumes with conventional pH probes[1]

System	Condition	Mixing Time(s)
Conventional rocker	Maximum speed and rock angle: 42 rpm, 10.4 °	50 to 98 seconds[2]
Allegro XRS 25 bioreactor system	75% maximum speed, bioreactor system maximum long axis angle, ⅓ short axis angle: 30 rpm, 15 ° long, 5 ° short	16 seconds

[1] Mixing trial results from three repetitions for each device.
[2] Times significantly different for edge/center measurements.

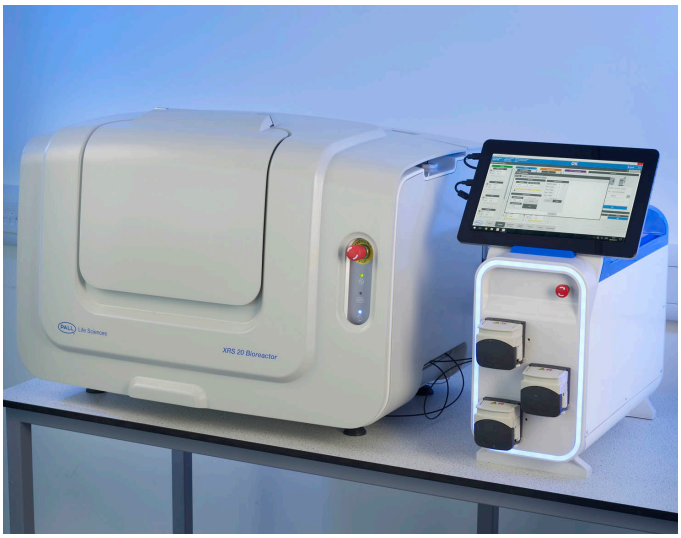


Table 2

Summary of mass transfer coefficients observed in 20 L working volumes as measured with nitrogen purge and recovery[3]

System	Condition	k_La per Hour
Conventional rocker	Maximum speed and angle: 42 rpm, 10.4 °	42
Allegro XRS 25 bioreactor system	40 rpm, 15 ° long, 15 ° short bioreactor system	73

[3] Mass transfer results from three repetitions for each device.

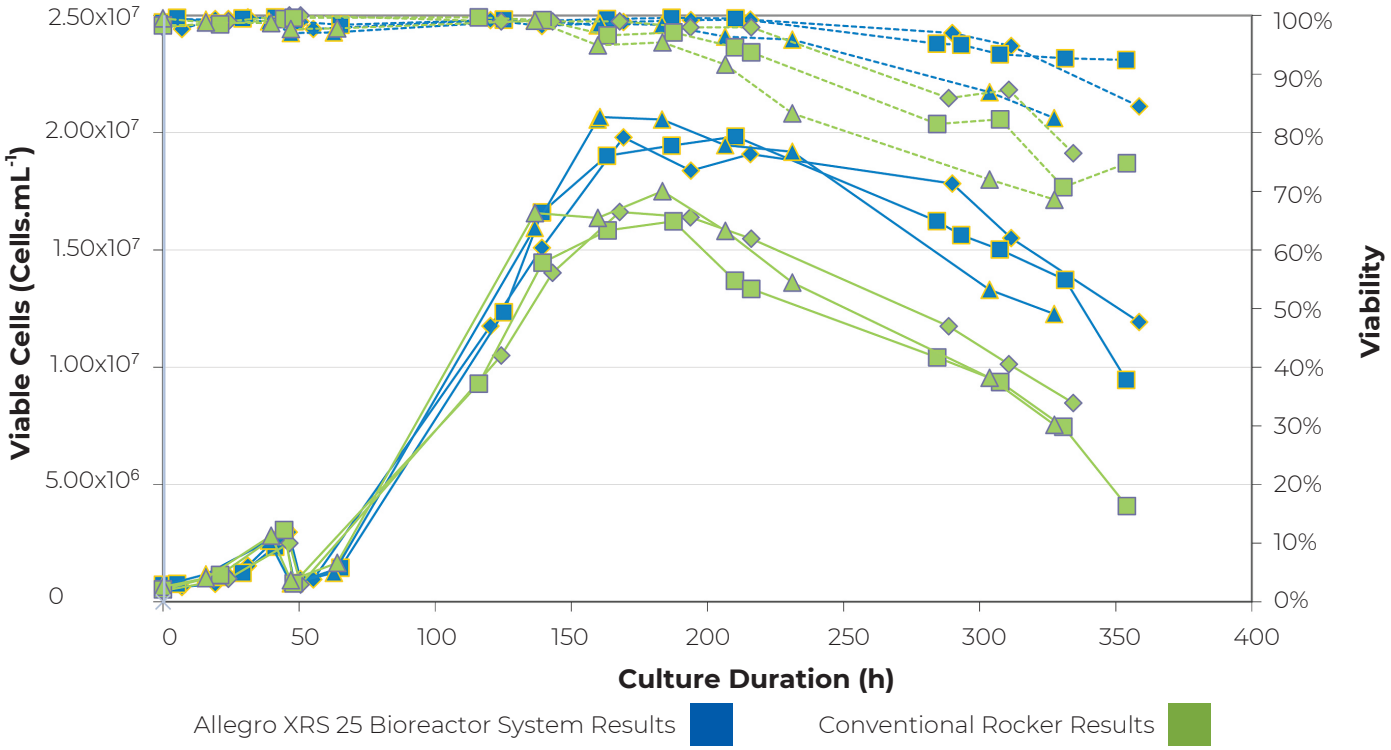
For additional details on mixing and mass transfer studies, see Pall application note USD 2899a: Performance Mapping in the Pall Allegro XRS 25 Bioreactor System.

Applications

The mixing properties of the 3D biocontainer bag design and bi-axial agitation lead 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 Allegro XRS 25 bioreactor system allows cells to attain higher densities, with higher overall viabilities, leading to significantly higher protein expression levels. In the batch culture example below (Figure 1), with identical media inputs and seeds, the Allegro XRS 25 bioreactor system produced 18% higher cell densities, and 30% more antibody titer compared to conventional rocker technologies.

Figure 1

Summary of side-by-side growth and viability experiments (n=3) at 20 L working volumes comparing conventional rocker system and Allegro XRS 25 bioreactor system. Simple batch culture of a chinese hamster ovary (CHO) cell line expressing a monoclonal antibody (mAb).



The excellent mixing properties of the Allegro XRS 25 bioreactor system have also shown to be beneficial for growing batch, fed batch and perfusion cultures of mammalian (CHO, hybridoma) and insect cells.

System Overview, Features and Benefits

Figure 2

Allegro XRS 25 bioreactor system – featuring the agitation platform, the single-use biocontainer bag and the mPath™ control tower with mPath Link supervisory control and data acquisition (SCADA) software package. The Allegro XRS 25 bioreactor system incorporates many features to ensure easy operation, robust performance, and suitability for cGMP operations.



Table 3

Allegro XRS 25 biocontainer bags

Feature	Benefit
3D biocontainer bag design	Superior mixing (with bi-axial platform), robust in operation
Biocontainer bag 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 cGMP operations
Integrated bottom drain with rotary lift valve	Improved suitability for cGMP operations, minimal hold-up volume, ease of use
Multiple liquid addition ports	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 bag built with Allegro film	Assurance of robustness, quality and supply, track record of use of film in cGMP operations, validation guide available

Table 4

Allegro XRS 25 Platform

Feature	Benefit
Bi-axial agitation (rocking motion on two horizontal axes at 90 ° 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

Table 5

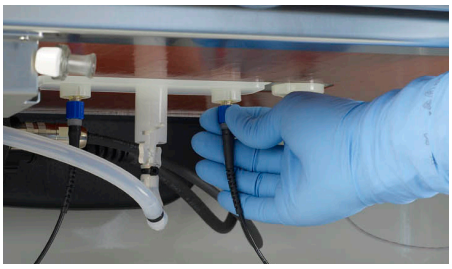
mPath Control Tower and mPath Link server

Feature	Benefit
mPath control tower designed for operation with mPath Link software– a SCADA software package	Capable of accessing data anywhere on any networked device including laboratory workstations, desktop computers, or remote devices such as laptops, mobile phones, and tablets
	Operates as either a standalone network or integrated with site IT systems, compatible with multiple network security approaches (e.g. virtual private network [VPN]) and password protection to protect bioreactors from unauthorized access
	Intuitive visual displays for easy interaction with bioreactors to calibrate components, set critical parameters, and fine tune process control
	Advanced trending capability including creation of custom trends of any process variable for both historic and live processes. Overlay and compare trends from multiple batches on one graph
	Database centric design supports naming, logging, and exporting batches for traceability and data analysis
	Full alarm customization to alert for process or safety critical events
	User-definable recipes including scheduling, version control and retirement for recipes no longer in use. Recipes can be multi-phased with user-defined transitions between each phase
	Compliance capability – designed for operation following 21 CFR Part 11/Annex 11 regulations

Table 5 (continued)

mPath Control Tower and mPath Link server

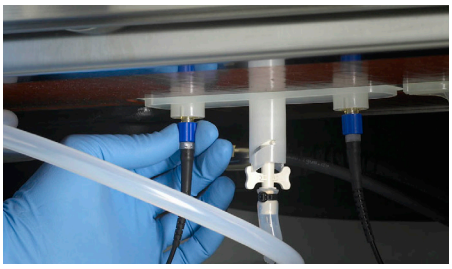
Feature	Benefit
Gas handling by six oxygen-rated thermal mass flow controllers (TMFCs) pre-calibrated for process gases	Accurate gas mixing for two gas streams enabling accurate parameter control and complex gas control regimes, each gas within the mix delivered by a dedicated TMFC
	Primary gas mix: N_2, O_2, air and CO_2
	Secondary gas mix: CO_2 and air
	Calibrated flow rates up to 1 L/min for each TMFC
	Onboard regulators ensure accuracy of TMFCs even with higher input pressures
	Onboard pressure sensors, combined with alarming capability enable notification of empty gas cylinders or biocontainer bag overpressure
	Fast fill button – quick and safe inflation of biocontainer bags with air
Liquid handling with three variable speed pumps, integrated load cells and biocontainer bag hangers	Accurate delivery of feeds and titrants without compromises, standard variable speed pumps enable smoother process control and feed profiles for less process variability
	8 mm max tubing outside diameter (OD)
	14 - 211 rpm (control requiring speeds less than 14 rpm achieved through pulse width modulation [PWM])
	Removable pump heads for easy cleaning and serviceability
	Removable biocontainer bag hangers with integrated load cells allow space efficient execution of weight based feed profiles and accurate tracking of titrant delivery
Ergonomic industrial design	Extensive human factors research to determine optimal placement of connections and control tower elements
	Flexibility in operation – choose when and where to view data, choose how to design processes
	Compact design to limit bench space requirements – small form factor and biocontainer bag hangers remove the need for scales and bottles
	Elevated from bench for cleanability



Tubing management system



In-process sampling



Drain and optical sensors

Customization

Pall has standard Allegro XRS 25 biocontainer bags equipped with all liquid and gas connections for the most typical processes and most operations. The three feed lines, the accessory line, and the drain are fitted with standard laboratory connections. Process liquids, including media and inoculum, can easily and safely be transferred into the bioreactor.

Pall can assist in customizing the bioreactor systems. This includes adding aseptic connectors (Kleenpak® sterile connectors), and small changes on the biocontainer bags up to and including integrating the bioreactor with all surrounding unit operations into a fully automated process.

Documentation and Certificates

The Allegro XRS bioreactor is delivered with complete documentation that qualifies the system. All units are tested prior to shipment and witnessed factory acceptance testing (FAT) is available on request.

The biocontainer bags are delivered with all the batch specific certificates and calibration information for the included single-use sensors.

Pall also can assist with hardware qualification, and standard installation verification (IV), operational verification (OV), FAT and site acceptance test (SAT) test protocols are available.

Pall Quality Standards

Pall maintains a very stringent approach to quality of purchased and manufactured components. Allegro bioreactor systems are designed and built to well recognized industry standards. The Allegro XRS 25 bioreactor system hardware meets many quality standards including:

- Good automated manufacturing practice (GAMP) current version
- 21 CFR Part 11 for electronic records
- Electromagnetic compatibility (EMC) to EN 61326-1: 2013 and FCC CFR 47 Part 15B: 2013
- The product is made in a manufacturing facility where the quality management system is ISO9001: 2008 certified.

A full list of quality standards is available on request

The Allegro XRS 25 biocontainer bag quality standards include:

- The product is made in a manufacturing facility where the quality management system is ISO13485 and ISO9001 certified
- 100% of Allegro XRS 25 biocontainer bags are checked for correct components, configuration, welding standard and dimensional correctness. A visual inspection confirms there are no embedded particles in the film or any loose particles inside or outside of the biocontainer bag
- 100% of Allegro XRS 25 biocontainer bag chambers undergo a pressure leak test during manufacturing
- Samples from each biocontainer bag manufacturing batch undergo a tensile test of the film weld area and a microscope inspection of the weld area to ensure the quality of the welded seal
- Fluid path endotoxins: periodically, rinse effluents from representative samples of Allegro systems are tested for endotoxins in accordance with USP <85> using limulus amoebocyte lysate (LAL) reagent. Fluid path rinses meet the internal specification of < 0.25 EU/mL
- Fluid path cleanliness: periodically, rinse effluents from representative samples of Allegro systems are tested for particulates. Fluid path rinses meet the current limits under USP <788> particulate matter in injections

The materials of construction of the Allegro XRS 25 biocontainer bag meet:

- USP <88> biological reactivity test *in vivo* for class VI - 50 °C plastics
- USP <87> biological reactivity tests *in vivo*, cytotoxicity
- USP <85> bacterial endotoxin tests
- USP <661> physico-chemical testing for plastics
- USP <788> particulate matter in injections

Materials of construction for all components in contact with fluid are TSE/BSE risk materials free.

All Allegro XRS 25 biocontainer bags are supplied double bagged (outer layer opaque to protect the single-use sensors from light) and irradiated at a minimum dose of 25 kGy.

Preventive Maintenance and Service Packages

The Allegro single-use bioreactor systems are supported with extensive maintenance and service packages. Pall has a global network of technicians and engineers available to assist with installation, qualification, training, technical support, preventive maintenance and on-site repairs. Contact Pall to arrange to discuss any of these services.

Pall Accelerator℠ process development services provide customers with expert advice and support for the implementation of fully integrated single-use processing solutions into new or existing processes, including process optimization, equipment selection, transfer of existing processes, scale-up and troubleshooting advice. Details can be found in the accelerator process development services brochure (USD 3079).

Preventive maintenance packages are available to ensure the continuous reliable operation of the Allegro XRS 25 bioreactor and to minimize downtime. Preventive maintenance typically includes a full functional test, exchange of wear parts, and calibration of all sensors.

General System Specifications

Table 6

General System Specification

Dimensions (W x D x H)	Controller	600 mm x 450 mm x 230 mm
	Platform	664 mm x 379 mm x 331 mm (allow for 200 mm lid overhang at the rear of the platform, and factor in an additional 370 mm for height when the lid is open)
Weight	Controller	20 kg
	Platform (with filled biocontainer bags)	78 kg (104 kg filled)
Gases	Gas connections	Inlet and outlet quick connectors 6 mm OD
	Gas flow control	TMFC
	TMFC pressurized air	0 - 1000 mL/min
	TMFC oxygen	0 - 1000 mL/min
	TMFC carbon dioxide	0 - 1000 mL/min
	TMFC nitrogen	0 - 1000 mL/min
Pumps	Quantity and connection	3 x variable speed peristaltic pumps, 0 - 211 rpm, maximum tubing OD 8 mm
Aeration	Inlet filter	0.2 µm single-use filter
	Gas delivery	Gas mix injected into biocontainer bag headspace
	Exhaust filter	0.2 µm single-use filter
	Exhaust heater	Silicone heater mat
Bi-Axial Agitation	Speed	1 - 35 rpm
	Angle	-15 to +15 degrees in both X and Y directions
	Control	Stepper motor controlled
Process	Working volumes	2 - 25 liters
	Temperature control	Heating blanket, ambient method convective cooling
	Temperature range	10 - 40 °C
	pH control	6 - 8, integrated single-use optical sensor
	Dissolved oxygen control	0 - 100%, integrated single-use optical sensor

The Allegro XRS 25 bioreactor system is available as a standard product; however, both the bioreactor hardware and consumables can be customized. Our teams are specialized in upstream and downstream processing and will gladly help find the right technology for any part of your manufacturing process. It is possible to combine the Allegro products to meet any requirement in the upstream part of the process:

- Media preparation
- Buffer preparation
- Media sterilization and aseptic transfer
- Liquid transfer into the bioreactor (e.g. glucose, anti-foam, base, etc.)
- Seed train solutions
- Cell harvest and separation
- Perfusion modules

Please contact Pall for a total solution discussion on your process.

Ordering Information

Description	Part Number
Allegro XRS 25 Bioreactor System: System hardware – consists of Allegro XRS 25 platform, mPath controller, control cables	XRS25BRS
mPath Link server and SCADA software	MPATHLINKV2
Standard Allegro XRS 25 biocontainer bag	609-40A
Accessory Manifolds:	
Main liquid addition/drain adaptor	6291-1612K
Allegro XRS 25 bioreactor system fed batch (⅛ in. ID) adaptor	6291-1612J
Allegro XRS 25 bioreactor system fed batch (3⁄16 in. ID) adaptor	6291-1612H

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