

Ambr[®] 250 High Throughput Perfusion

Fast Track Intensified Cell Culture Processes Simplifying Progress

SARTURIUS

Ambr® 250 High Throughput Perfusion

A Fully-Automated Bioreactor System for Intensified Cell Culture Process Development

Ambr® 250 High Throughout Perfusion is a parallel bioreactor system for rapid development of scalable perfusion processes using 100 – 250 mL single-use bioreactors and a fully automated liquid handling platform. The system supports the typical range of hollow fibre cell retention applications, with up to 24 fully single-use perfusion bioreactors in parallel. This step change in perfusion process development capability dramatically accelerates optimization of intensified cell culture processes leading to lower production volumes and reduced cost of goods.

Productivity

Ambr[®] 250 dramatically improves laboratory productivity, enabling cell culture scientists to carry out many times more perfusion culture experiments and full DoE experiments at a fraction of the cost compared with traditional perfusion-enabled benchtop bioreactors.

Wide Range of Fed-Batch and Perfusion Culture Conditions

Perfusion cultures can be fully optimized over a wide range of important parameters, including target cell density, crossflow rate, perfusion rate, bleed volume, bleed frequency and filter type, as well as typical culture and bioreactor process conditions such as clone, media, pH, temperature, RPM and gas flows.

The Ambr[®] 250 High Throughput Perfusion system is also capable of operating in fed-batch mode using standard Ambr[®] 250 bioreactors.

Scalability

With the industry standard Ambr® 250 High Throughput mammalian cell culture bioreactor at its core, the Ambr® 250 High Throughput Perfusion system can provide highly predictive and scalable performance for fed-batch cultures, and has equivalent potential for perfusion processes.

Convenience

The fully automated liquid handler carries out bioreactor sampling and reagent additions, saving hours of process support time. Fully integrated single-use perfusion bioreactors dramatically reduce setup, cleaning and turnaround time, decreasing cost per experiment and allowing high system utilization with minimal development timelines.

\bigoplus For more information, please visit

www.sartorius.com/en/products/fermentation-bioreactors/ambr-multi-parallel-bioreactors/ambr-250-high-throughput-perfusion



System Features

The Ambr® 250 High Throughput Perfusion System Combines 12 or 24 Bioreactor Stations, Integrated Perfusion Pumps, Bleed and Permeate Collection with a Fully Automated Platform



2

Automated liquid handler

The fully automated liquid handler carries out bioreactor sampling and liquid additions, significantly reducing manual operator interactions.

Integrated analytics

The liquid handler transfers samples to a range of optional integrated analyzers, enabling fully automated real-time feedback control loops based on these at-line assays. Optional analyzers: Ambr[®] Analysis Module; BioProfile FLEX2; Vi-CELL BLU Analyzer; Cedex HiRes.

For more information, please visit

www.sartorius.com/en/products/fermentationbioreactors/ambr-multi-parallel-bioreactors/ ambr-250-high-throughput-perfusion





3. Bioreactor station array

12 or 24 bioreactor stations in parallel with full individual process control, offers convenient set-up and simplifies running of full DOE experiments.

4. Permeate and bleed flow control and collection system

The system includes perfusion crossflow and permeate pumps, automated bleed functions, and both permeate and bleed fluid collection sets with collection bag and tubing management features. Also includes a walk-away permeate sampling system for samples up to 10 mL.

Integrated biological safety cabinet

A class II biological safety cabinet designed to maintain an aseptic environment even during robot manipulation of bioreactors, significantly reducing any risk of process contamination.

6.

Perfusion towers

Perfusion towers support and control key elements of the Ambr® 250 singleuse perfusion bioreactors such as the perfusion pump chambers, pinch valve cassette and perfusion filter.

Bioreactor Vessels

Ambr® 250 High Throughput Single-Use Perfusion Bioreactors Include All Components Required for Perfusion Culture, Fully Assembled and Irradiated

Single-use perfusion bioreactors significantly reduce staff time needed for set-up and cleaning, and enable rapid system turnaround, increasing system utilization, efficiency and reducing development timelines. Fully assembled and irradiated components further reduce set-up time and minimize risk of lost experiments.

Bioreactor key features

Core features in Ambr[®] 250 High Throughput Perfusion bioreactors which are also present in standard mammalian cell culture bioreactors include:

- 100-250 mL working volume with baffles
- Dual 26 mm pitched blade impeller
- Spot-based DO sensor
- Disposable pH electrode
- Integrated gas inlet and outlet filters
- Robotic compatible cap for sampling
- Sparger and headspace gassing options
- Integrated exhaust gas condenser

1. Bioreactor perfusion features

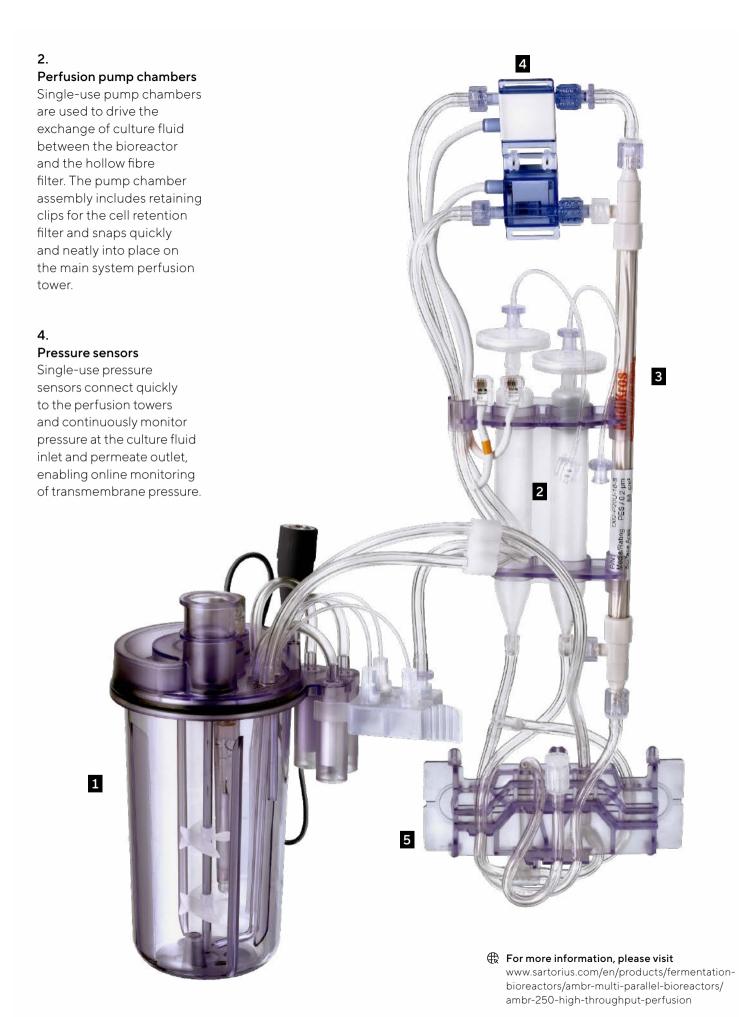
The single-use perfusion bioreactor includes a high efficiency multi-hole sparger capable of supporting very high cell densities. Two dip tubes allow flow of culture to and from the perfusion pump and filter, plus automated bleeding and bleed-to-level functions.

3. Cell retention filter

The industry standard approach to cell retention, using a hollow fibre membrane. Options include a $0.2 \, \mu m$ or a $30 \, kDa$ filter as standard, and the filter can also be changed by the user before or during the experiment.

5. Pinch valve cassette

The single-use pinch valve cassette slots into place on the Ambr® 250 deck at the base of the perfusion tower. Four pinch valves guide the flow of fluids through the perfusion tubing set and enable automated bleeding functions.



Functions

The System Performs Many Fully Automated Functions

Bioreactor controller

- Three gasses per bioreactor with mass flow sensing of the mixed gas flow:
 - O₂
 - CO₂
 - N₂/air
- Four positive displacement liquid pumps per bioreactor for high precision at low flow rates
- When operating with perfusion bioreactors, three pumps are available for reagent addition to the bioreactor and the fourth liquid pump is used to direct permeate flow from the perfusion filter to a collection bag
- For fed-batch operation using standard Ambr® 250
 High Throughput bioreactors, all four liquid pumps are
 available for reagent additions to the bioreactor
- Individual bioreactor temperature control with heating or cooling
- Individual impeller speed control per bioreactor
- Optional exhaust gas monitoring for O₂ and CO₂
- Integrated CIP | SIP protocols for fluid pumps and liquid lines (via optional autoCIP module)

Perfusion tower

- Ergonomic 'easy connect' design for rapid installation of single-use perfusion bioreactors including all single-use perfusion components
- Perfusion culture crossflow pumps for each bioreactor provide individual control of perfusion flowrates
- Pinch valve system controls fluid flow between the bioreactor and perfusion filter, and automatically routes bleed fluid to a collection bag
- Online pressure monitoring at perfusion filter inlet and permeate outlet enable monitoring of transmembrane pressure
- Integrated perfusion tower heaters

Applications

Ambr® 250 High Throughput Perfusion is capable of running in either perfusion culture or fed-batch mode, depending on the type of Ambr 250® High Throughput bioreactors installed. The system is able to cover a wide range of applications in biopharma development, including but not limited to perfusion process operations.

- Perfusion process clone selection
- Perfusion media development
- Perfusion process optimization
- Perfusion process characterization
- Perfusion process scale down model development



Scalability

Single-Use from Cell Line and Process Development to Production Scale

- Geometrical similarity of vessel design
- Consistent mixing and gassing strategies
- High performance gas transfer and mixing
- Reliable single-use platforms

BioPAT® Process Insights

Included with the Ambr® 250 High Throughput system is a 1 year license of BioPAT® Process Insights software application.

BioPAT® Process Insights enables predictive scale conversion and low risk process transfer between supported Sartorius bioreactors: Ambr® 15 and 250, Univessel® SU and Glass and Biostat STR® 50-2000 L.

BioPAT® Process Insights is a standalone, on-premise software application. Each license permits up to 10 concurrent users (seats). License includes maintenance, technical support and any available software releases during the active license period. A new license is required after 1 year to continue usage of the software. Please check the technical specification for minimum computer hardware and software specification requirements.









Ambr[®] 250 High Throughput Perfusion

Biostat® B Univessel® SU 2L

Biostat STR® 50

Biostat STR® 200

Similar Geometry and Sensors

———— Process Development and Characterization —————

\bigoplus For more information, please visit



Ambr[®] 250 High Throughput Perfusion



Biostat® B-DCU with Univessel® Glass 1 - 10 L



Biostat® D-DCU 10 - 200 L

Also scalable to multi-use technologies -



Biostat STR® 500



Biostat STR® 1000



Biostat STR® 2000

- scaling up from 0.25 L to 2000 L

Production —

Germany

Sartorius Stedim Biotech GmbH August-Spindler-Strasse 11 37079 Goettingen Phone +49 551 308 0

For further contacts, visit www.sartorius.com

USA

Sartorius Stedim North America Inc. 565 Johnson Avenue Bohemia, NY 11716 Toll-Free +1 800 368 7178