

ambr[®] 250 modular Single-Use Benchtop Bioreactor with Simplified Operation for Increased Productivity



New Advanced Benchtop Bioreactor System for Parallel Microbial and Cell Culture

ambr[®] 250 modular is an innovative new high performance benchtop bioreactor system for parallel microbial or cell culture in 100 - 250 mL single-use vessels. The system utilizes the same advanced stirred tank bioreactor technology pioneered in the original ambr[®] 250 high throughput system. The system comprizes a series of elegantly designed benchtop modules enabling 1 to 8 bioreactors to be operated in parallel and a control module with intuitive system software accessed via a user-interface screen.

Productivity

Each single-use bioreactor vessel is fully integrated with sensors, liquid reservoirs and syringe pumps which make it possible for experiments to be set up and turned around rapidly. A single user can operate up to 8 bioreactors at a time.

Scalability

Because the bioreactor vessels are geometrically similar to larger bioreactors, all processes on the system can be scaled up to those of large bioreactors making for optimum scalability.

• Ease-of Use

Due to the unique integrated single-use design of the vessel, with probes, pumps and reservoirs the user can focus on the process and not the set-up. There is no need to connect multiple tubes or filters or to autoclave the vessels and accessories.

Expandable

The modularity of the system means that it can be extended to meet the needs of an expanding company.



New ambr[®] 250 modular



ambr[®] 250 modular System Combines 1 to 8 Bioreactor Stations and a Control Module with System Software



The modular design is expandable up to 8 bioreactors.

Bioreactor module

Holds 2 bioreactor stations. Up to 4 modules can be connected to the controller.

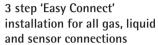


Fast-loading peristaltic pump

Accessible for each bioreactor, provides an alternative route for feeding and harvesting. This is in addition to the 5 integrated syringe pumps in each bioreactor.



Chilled liquid reservoir Chills liquids to temperatures between 6-8°C ensuring temperature sensitive media can be maintained.



- Step 1 slot in
- Step 2 secure with clamp
- Step 3 secure pH connector Enabling quick set-up and rapid turnaround.

sartorius stedim ambr 250

Touch screen user-interface Enabling easy control and supervision of multiple bioreactors.

Bioreactor controller Manages all processes including

pH, temperature and DO for up to 8 bioreactors. Fully integrated foam control.

Optional off-gas analyzer Monitors and controls processes using data from individual bioreactors' exhaust gases.

ambr® 250 modular Bioreactor Vessels

Each bioreactor is fully integrated with 5 liquid reservoirs and proprietary single-use syringe pumps. The integration simplifies experimental set-up, eliminates any need for vessel sterilization, and significantly reduces any error due to manual handling.

Vessel scalability

Vessels are geometrically similar to standard bench and pilot scale bioreactors, enabling straightforward scale-up.

Single-use mammalian or microbial bioreactors

- 100 250 mL working volume.
- Dual pitch blade or Rushton impellers.
- Spot based DO sensor.
- Disposable pH electrode.
- Integrated gas inlet filters.
- Sparge and headspace gassing options.
- Integrated exhaust gas condenser.

Integrated liquid reservoirs

- 2 Integrated 125 mL reservoirs per bioreactor
- 3 Integrated 50 mL. Reservoirs per bioreactor.

Single-use syringe pumps
Each reservoir is integrated to its
own high precision syringe pump
allowing for highly consistent and
accurate liquid delivery.



Fully integrated liquid

Gas tube

Gases can either be delivered into the headspace or sparged into the media. These delivery systems are independent and can function in parallel.



New Unbaffled Single-Impeller Vessel

This vessel type has been developed for microcarrier and regenerative medicine applications. The design is optimized to provide gentle mixing, good culture circulation and efficient resuspension of microcarriers or aggregates, especially when running very gentle agitation conditions i.e. low stirring speeds.



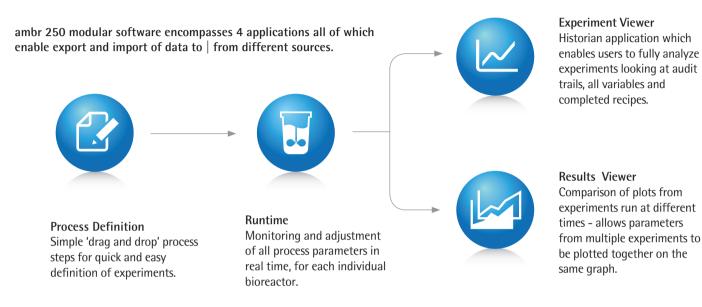
Single impeller
The large pitched
blade impeller near
the bottom of the
vessel provides
effective and gentle
mixing at low stirring
speeds.

Unbaffled vessel Removing baffles from the side wall maximizes fluid circulation at the base of the vessel at low stirring speeds. This ensures microcarriers or aggregates remain suspended and well mixed during very gentle low speed mixing.

Single-use pH and DO sensors Both pre-calibrated, the DO spot measures 0 - 200% and the standard pH probe has a measurement range of 2 - 8.5. Double impeller - Rushton or pitch-blade For microbial or mammalian vessels respectively.

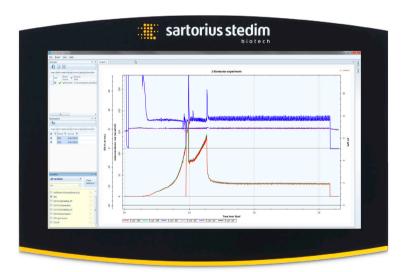
Software

ambr[®] 250 modular is supplied with the same advanced software as the established ambr 250 high throughput system. Users can design new and complex experiments and analyze results easily and quickly.



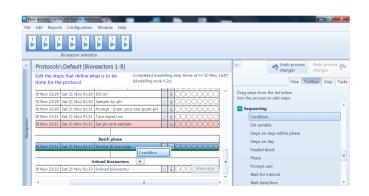
Touchscreen interface

The ambr 250 modular system controller is operated via an intuitive touchscreen interface, ensuring user interactions are ergonomic and efficient.



Multi-parallel design

The ambr 250 software has been developed especially for multiparallel bioreactor operation, and provides efficient workflows for process set up, monitoring and other user interactions.



Functions

ambr® 250 modular automatically controls and adds liquids to 1 to 8 bioreactor | fermenter vessels in parallel

Bioreactor controller

- Three gasses per bioreactor with mass flow sensor:
- Mammalian
 - -0_{2}
 - CO₂
- N₂ | air
- Microbial
 - -0_{2}
 - Air
 - N₂
- Five positive displacement liquid pumps per bioreactor for high precision at low flow rates.
- Individual bioreactor temperature control with heating and cooling.
- Individual impeller speed control per bioreactor.
- Optional off-gas analysis by BioPAT ambr Xgas for CO₂ and O₂, also uses OUR and CER measurements.

Applications

ambr® 250 modular is configurable for microbial or mammalian cell culture and is used in R&D across biopharm and industrial biotech for the following applications:

- Process optimization.
- Process characterization.
- Process robustness experimentation in support of QbD studies.
- Process scale-down model.

Regenerative Medicine

ambr 250 has been applied very widely in biopharma as a predictive and scalable process development tool, reducing timelines, applying DoE and QbD, and improving productivity and product quality.

ambr 250 is also an effective process development model for Regenerative Medicine applications, and can be used to rapidly and efficiently develop processes for a wide range of therapies and cell types. Optimized processes can be scaled up or scaled out into the chosen production system for manufacture of clinical material, such as Sartorius Biostat® RM TX or Biostat® STR bioreactors



Scalability

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

- Geometrical similarity of vessel design
- Consistent mixing and gassing strategies
- Reliable single-use platform









ambr[®] 250 modular

BIOSTAT® B UniVessel® SU 2L BIOSTAT STR® 50

BIOSTAT STR® 200

Similar geometry and sensors -

Process development



ambr[®] 250 modular



BIOSTAT® B-DCU with UniVessel® Glass 1 - 10 L



BIOSTAT® D-DCU 10 - 200 L

Also scalable to glass and stainless steel bioreactors



BIOSTAT STR® 500

BIOSTAT STR® 1000

BIOSTAT STR® 2000

scaling up from 0.25 L to 1000 L

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