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Enhancing Bioprocess Scalability With the Univessel® SU 10 L: Implementing CHO Cell Process Intensification From Development to Commercial Scale

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Abstract

In the rapidly evolving field of bioprocessing, process intensification has become a key strategy to optimize operations and increase productivity. Readily scalable processes are essential to translate process development results to manufacturing while ensuring consistent product quality.

This application note demonstrates the implementation of process intensification strategies across small-, bench-, and commercial-scale bioreactor platforms and highlights the resulting performance benefits. The Univessel® SU 10 L bench-scale bioreactor was used to enable scalable process transfer and integration into process development and clinical | commercial manufacturing workflows, with the 4Cell® SmartCHO media system further enhancing cell growth and productivity.

The results confirm consistent performance across the Sartorius bioreactor portfolio, including the Univessel® SU 10 L, and demonstrate its role in bridging small- and large-scale systems through scalable, standardized processes.



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Introduction

Scalability is a critical factor that can determine the success of a production process. As biopharmaceutical companies strive to meet increasing cost pressures, the ability to efficiently transfer processes from laboratory to production scale becomes paramount.

An N-1 perfusion process is an innovative process intensification strategy that enhances the efficiency and productivity of bioprocessing operations. By intensifying the seed train, higher cell densities can be reached in smaller bioreactor volumes, facilitating substantial reductions in inoculation volumes into the production bioreactor (up to ~30× reduction compared with conventional fed-batch seed trains). Importantly, intensified N-1 perfusion processes have been shown to generate cultures and products with characteristics comparable to batch-phase seed train procedures, supporting implementation without compromising product quality. As a result, seed train intensification can simplify bioprocess operations by shortening the overall workflow duration while maintaining process robustness and consistency.¹

The new Univessel® SU 10 L Perfusion vessel is ideally suited to process intensification, and in this case, to implement an N-1 perfusion process. Its comprehensive set of product features can support a broad range of modern mammalian cell processes. The vessels are irradiated and ready to use, offering substantial time savings over traditional glass bioreactors. Crucially, Univessel® SU 10 L benchtop bioreactors are geometrically consistent with the broader Sartorius bioreactor portfolio, ensuring smooth scalability. They are also available for research or manufacturing use, meaning they can be easily integrated into both process development applications and GMP manufacturing environments.

This application note demonstrates the feasibility of implementing a scalable N-1 perfusion process using the Univessel® SU 10 L Perfusion bioreactor. By comparing the Univessel® SU 10 L Perfusion bioreactor with the Ambr® 250 High Throughput and Biostat STR® 50 L systems in a perfusion setting, the study shows how shared performance attributes can support consistent process transfer across production volumes while enabling standardization and efficiency. Together with Sartorius bioreactor systems, the 4Cell® SmartCHO media system supported robust, high-performance cell culture in perfusion mode.

Through detailed analysis of experimental data, this application note provides insight into process engineering and a replicable framework for enhancing bioprocessing capabilities.

Materials & Methods

Experimental design

The experiment was conducted using Ambr® 250 High Throughput, Biostat STR® 50 L, and Univessel® SU 10 L bioreactors. The process parameters used are shown in Table 1.

Table 1: General process parameters

Parameter	Specification	
Cell line	CHO DG44 (Sartorius)	
Initial cell density	2.5 × 10 ⁶ cells/mL	
Medium	4Cell® SmartCHO media system	
Temperature setpoint [°C]	36.8	
pH setpoint	7.1	
Agitation speed [rpm]	Ambr® 250 High Throughput	Min: 855 Max: 1,320
	Univessel® SU 10 L	Min: 274 Max: 406
	Biostat STR® 50 L	Min: 160 Max: 240
Tip speed [m/s]	1.8	
Dissolved oxygen setpoint [%]	40	

Univessel® SU 10 L control system

Continuous real-time monitoring of key parameters such as temperature, pH (Table 2), and dissolved oxygen (DO; Figure 1 and Table 3) was performed throughout the process, and the Sartorius Bioreactor Data Control Unit (Biostat® B-DCU) and Biobrain® Supervise (previously known as MFCS 4) were employed to maintain optimal conditions. These control systems ensured consistent conditions by automatically adjusting settings based on real-time data.

Table 2: pH PID parameters for Univessel® SU 10 L

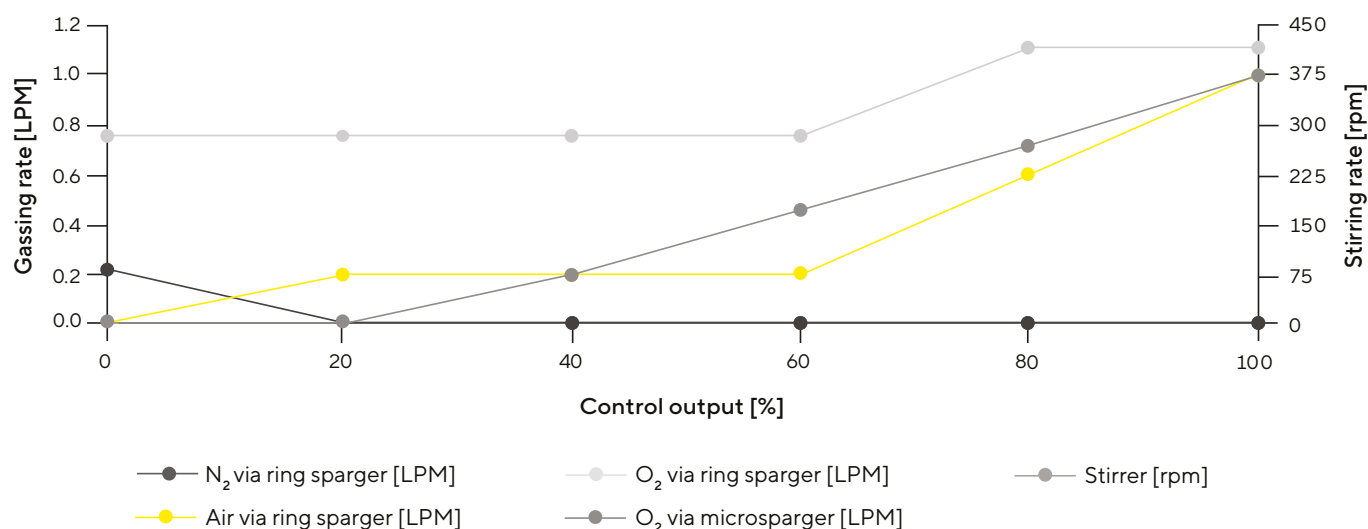
Parameter	Value
pH setpoint	7.1
Sampling rate [s]	60
XP [%]	60
Ti [s]	600
TD [s]	50
Min [%]	0
Max [%]	50
Db [%]	0

Note. XP = proportional band, Ti = integral time, TD = derivative time, Db = deadband

Table 3: DO PID parameters for Univessel® SU 10 L

Parameter	Value
DO setpoint [%]	40
Sampling rate [s]	10
XP [%]	200
Ti [s]	1,000
TD [s]	0
Min [%]	0
Max [%]	100
Db [%]	0

Note. XP = proportional band, Ti = integral time, TD = derivative time, Db = deadband

Figure 1: DO control strategy for Univessel® SU 10 L

Media platform

The 4Cell® SmartCHO media system was used to support cell growth and productivity. This media system is specifically formulated for high cell density perfusion processes, with enhanced nutrient profiles to support robust proliferation and viability. It also enables efficient perfusion processes by reducing the need for high media exchange rates.

Perfusion process

The bench-scale perfusion process used the Repligen XCell ATF® 2 system. The process parameters for the Univessel® SU 10 L Perfusion were established according to the specifications detailed in Table 4. Following a three-day initial batch phase, perfusion was initiated at a rate of 0.25 vessel volumes per day (VVD) when cell density reached 2.5×10^6 cells/mL. Over the following six days, online cell density was measured using BioPAT® Viamass, and the perfusion medium exchange rate was adjusted to maintain a cell-specific perfusion rate (CSPR) of 40 pL/cell/day and target a final cell density of 80×10^6 cells/mL. The same process and parameters were also applied to the Ambr® 250 High Throughput and Biostat STR® 50 L scales.

Results and Discussion

Table 4: Perfusion process parameters for Univessel® SU 10 L

Parameter	Specification
VVD	Min: 0.25 Max: 4
CSPR [pL/cell/day]	40
Perfusion control	Volumetric
Target cell density ($\times 10^4$ cells/mL)	80
Perfusion start	Day 3

Process analytical technology

BioPAT® Viamass was used as an in-line biomass sensor to continuously monitor viable cell concentration during the N-1 perfusion process. The real-time viable cell density measurement enabled tighter control of cell growth, more accurate adjustment of perfusion rates, and improved comparability across scales by aligning transfers and setpoints based on an online rather than a purely offline parameter. This approach reduced reliance on manual sampling and supported a more consistent, automated seed train intensification strategy.

For the Biostat STR® 50 L runs, the BioPAT® Viamass single-use configuration was implemented with the single-use Biostat STR® bag. BioPAT® Viamass is now available as an integrated single-use solution in the Ambr® 250 High Throughput Generation 2 system, where the sensor is incorporated directly into the vessels, further facilitating seamless at-line | online biomass monitoring across the Sartorius bioreactor portfolio.

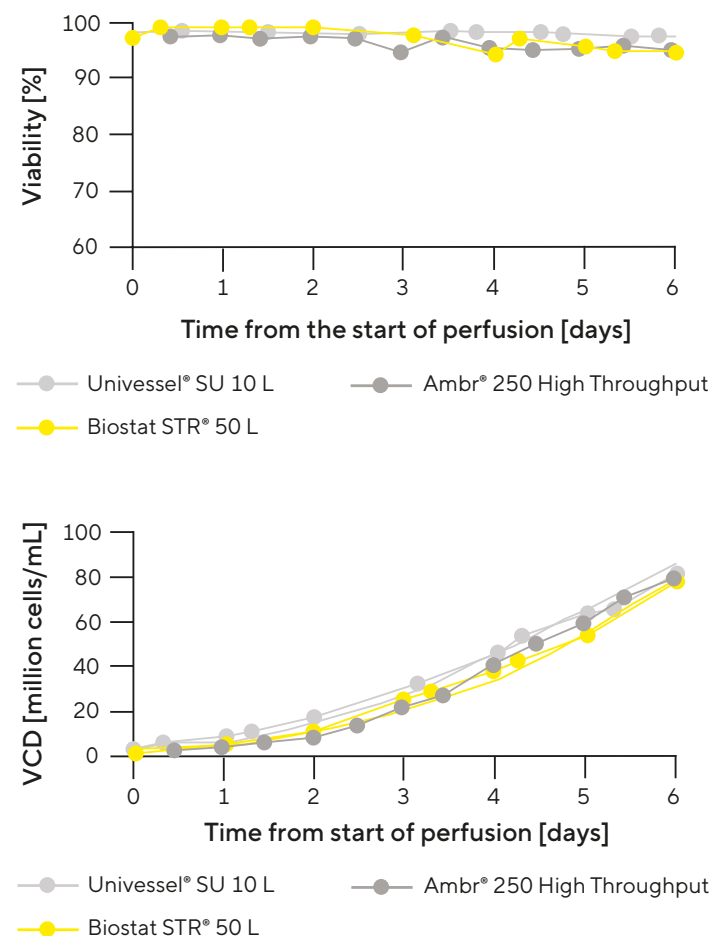
Harmonized data collection across scales

Biobrain® Supervise was used to collect batch data (temperature, DO, pH, etc.), BioPAT® Viamass was used to collect online capacitance measurements, and BioProfile® FLEX 2 was used to collect metabolites and viable cell density (VCD) data.

Scalability of cell growth dynamics

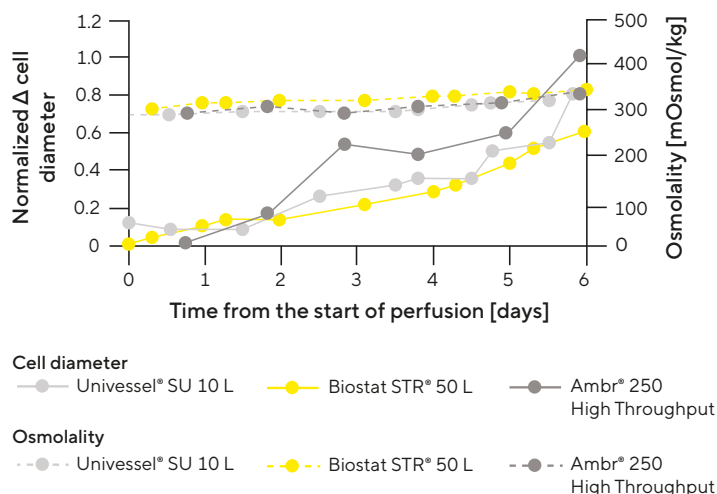
Scalable cell growth was demonstrated across Ambr® 250 High Throughput, Univessel® SU 10 L, and Biostat STR® 50 L bioreactors. Figure 2 shows that the Univessel® SU 10 L achieved VCDs comparable to larger-scale platforms, reaching the target cell density of 80×10^6 cells/mL by Day 6. Cell viability (Figure 2) and cell diameter (Figure 3) were consistently maintained throughout the run, indicating sustained culture health and uniform cell morphology, respectively. The run was concluded once the desired cell density was reached, demonstrating the ability of the Univessel® SU 10 L to sustain high-density cultures without compromising cell quality. These results confirm the scalability of the Univessel® SU 10 L and its suitability as a reliable platform for bioprocessing applications.

Figure 2: Viable cell density and viability across Ambr® 250 High Throughput, Univessel® SU 10 L, and Biostat STR® 50 L cultures from Day 3, the start of perfusion



Note. The trend lines without markers on the VCD plot are online capacitance measurements from BioPAT® Viamass translated into online VCD.

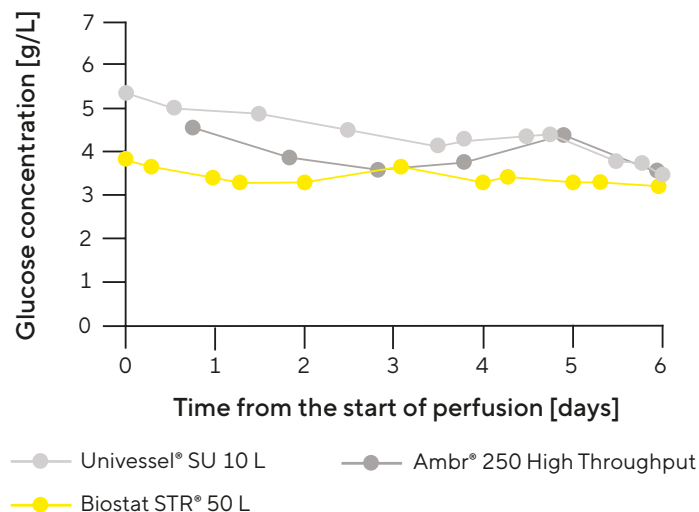
Figure 3: Average cell diameter and osmolality across Ambr® 250 High Throughput, Univessel® SU 10 L, and Biostat STR® 50 L cultures from Day 3, the start of perfusion



Metabolite profiles in bioreactor and permeate

During the perfusion process, osmolality and key metabolites, including glutamine, glucose, glutamate, and lactate, were effectively managed. The consistent levels of these metabolites across all scales demonstrate that the Univessel® SU 10 L bioreactor, in conjunction with the 4Cell® SmartCHO media system, provides an optimal environment for high-density cell cultures, ensuring efficient nutrient utilization. Figure 4 shows that glucose concentrations were consistently maintained across the Univessel® SU 10 L, Ambr® 250 High Throughput, and Biostat STR® 50 L bioreactors, further emphasizing process robustness across the bioreactor platforms.

Figure 4: Glucose trends across Ambr® 250 High Throughput, Univessel® SU 10 L, and Biostat STR® 50 L cultures from Day 3, the start of perfusion

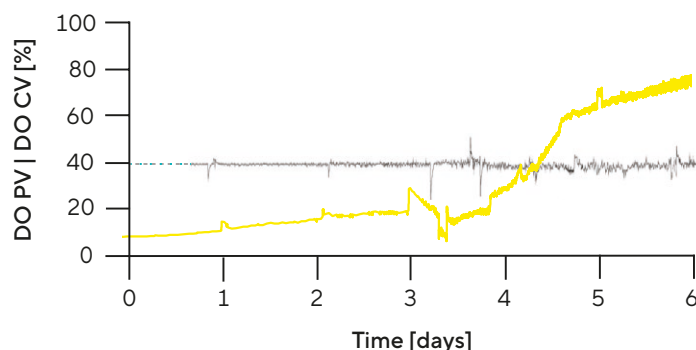


DO controller output scalability

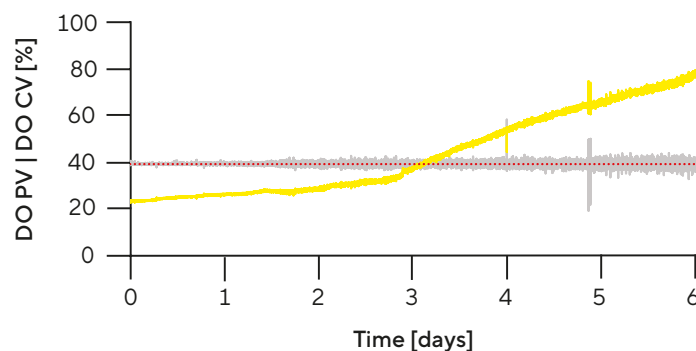
Figure 5 shows the DO profiles for the Univessel® SU 10 L and Biostat STR® 50 L from the start of perfusion. The data illustrate that the similar geometries and sparger configurations of the two bioreactors, combined with a consistent DO control strategy, enabled tight control of the DO setpoint and produced a predictable DO controller output profile across the defined operating ranges of stir speed, air, oxygen, and nitrogen.

Figure 5: DO trends across Univessel® SU 10 L and Biostat STR® 50 L cultures from Day 3, the start of perfusion

Univessel® SU 10 L



Biostat® STR® 50 L



Conclusion

The Univessel® SU 10 L bioreactor has demonstrated its effectiveness as a scalable solution for bioprocessing, achieving the desired cell densities and metabolite profiles consistent with other process scales. These results confirm that the Sartorius bioreactor portfolio can efficiently support high-density cultures, with stable cell viability and morphology further affirming robust performance and scalability.

The Sartorius bioreactor portfolio is scalable by design: consistent geometric vessel designs across the Ambr® 250 High Throughput, Univessel® SU 10 L, and Biostat® STR® platforms enable seamless process transfer, as demonstrated here with an industrially relevant N-1 perfusion process. Automated bioreactors like the Ambr® 250 High Throughput facilitate multi-parallel experiments to identify ideal process conditions, while the Univessel® SU 10 L allows implementation at the bench scale, enabling further process investigation and optimization and generating relevant product material for downstream processing studies or clinical trials. Intensified processes can then be scaled up using the Biostat® STR® portfolio, with integration of XCell ATF® technology into the Biobrain® platform streamlining operational efforts.

This application note provides a reproducible framework for implementing process intensification across scales. The Univessel® SU 10 L represents a new solution for advancing bioprocessing strategies and unlocking new possibilities in the field.

References

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