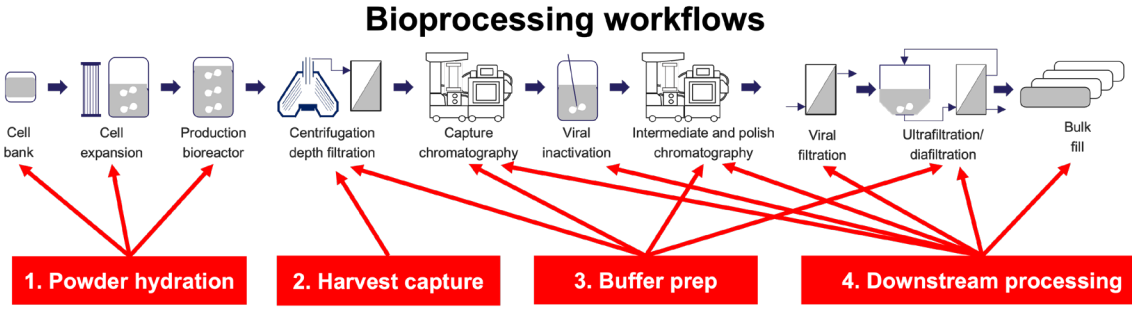
Bioprocessing

Efficient mixing from 30 L to 5,000 L for bioprocessing applications with the imPULSE Single-Use Mixer

Introduction

Mixers are essential for combining process ingredients and maintaining uniform temperatures, pH levels, and concentrations in various bioprocessing workflows to support product quality and consistency (Figure 1). Single-use mixers are ideal for manufacturing biologic medicines because they offer a unique balance of scalability, flexibility, and efficiency.



Mixing applications

Figure 1. Mixing is essential for many bioprocessing unit operations.

Thermo Fisher Scientific has a comprehensive portfolio of efficient and powerful single-use mixers to address a variety of bioprocessing mixing needs. The Thermo Scientific™ imPULSE™ Single-Use Mixer (S.U.M.) stands out for its ability to quickly and efficiently mix media, buffers, and other bioprocess fluids in volumes ranging from 30 L to 5,000 L. The imPULSE S.U.M. features an innovative reciprocating mixing disc that drives fluid down along the central axis of the mixer column and up around the outer walls for continuous circulation (Figure 2). This mixing mechanism minimizes foaming and vortexing and enables mixing at small working volumes. The imPULSE S.U.M. also features a range of mixing speeds for gentle as well as vigorous applications.

The integrated touchscreen console on the imPULSE S.U.M. supports advanced agitation control and automatic data logging for critical process parameters like pH, conductivity, and temperature. User-defined recipes can be utilized to automate processes further, thereby enhancing efficiency. The bioprocess containers for the imPULSE S.U.M. are designed for easy draining with minimal holdup volume, maximizing recovery of valuable product at every process stage.

This technical note describes the performance capabilities of the imPULSE S.U.M. based on computational fluid dynamics (CFD) and empirical mixing data that demonstrate its effectiveness for various bioprocessing applications.

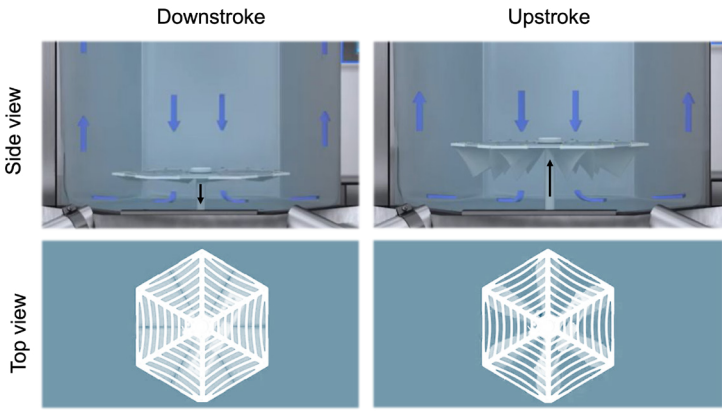


Figure 2. Side and top views of the mixing disc during upstroke and downstroke. The black arrows indicate disc motion, and the blue arrows indicate fluid motion. Flexible flaps are attached to the underside of the hexagonal mixing disc. The flaps close during the downstroke to create a down-pumping mechanism and open during the upstroke to allow fluid to continue moving downward as the mixing disc repositions for the next downstroke.

Mixing performance

The CFD streamline plot in Figure 3 shows that fluid motion in the imPULSE S.U.M. is distributed throughout the vessel, and experimental measurements of flow speed have confirmed this broad distribution. Rapid T95 mixing times of less than 2 minutes demonstrate the ability of the imPULSE S.U.M. to quickly eliminate concentration gradients, promoting uniform composition. To facilitate hydration of powdered media, the imPULSE S.U.M. features a fluid recirculating loop that terminates in a spray nozzle at the top of the bioprocess container. Fluid from the spray nozzle actively hydrates and disperses powders, leading to faster dissolution times.

Results

The imPULSE S.U.M. offers continuous and rapid mixing. In two studies, we performed mixing over a range of volumes using concentrated tracer salts and conducted liquid-solid hydration tests [1,2]. The T95 mixing time for tracer tests is defined as the time required for all conductivity sensors to stabilize within 95% of the final concentration. The T95 mixing times for the liquid-solid tests shown in Table 1 are based on data collected with online sensors or in offline measurements (e.g., glucose concentration, pH, osmolality) [2].

Conclusion

The imPULSE Single-Use Mixer (S.U.M.) demonstrates exceptional mixing performance at volumes ranging from 30 L to 5,000 L in a variety of bioprocessing applications. Empirical data and CFD analyses have confirmed that the imPULSE S.U.M. can address diverse bioprocessing requirements, making it a versatile and reliable solution for modern bioprocessing workflows.

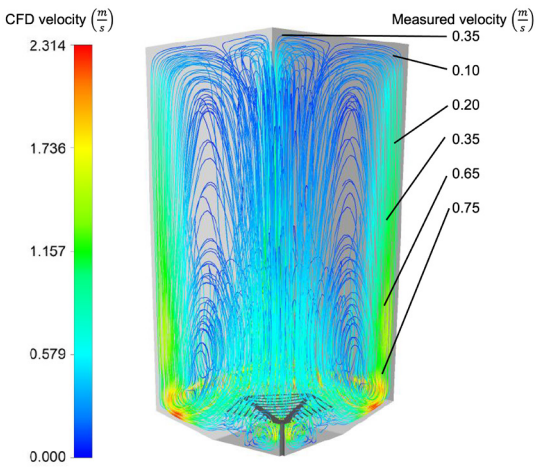


Figure 3. CFD streamline plot showing the 5,000 L imPULSE S.U.M. during an upstroke after 6 seconds of mixing. The fluid path traces are colored according to fluid velocity as shown on the left axis. The locations of flow speed measurements (±0.05 m/s) collected with a knot meter sensor are shown on the right.

Table 1. imPULSE S.U.M. T95 mixing times for different bioprocessing applications.

Test	Mixing time
Liquid-liquid	≤2 min
Liquid-solid (salt granules)	≤9 min
Liquid-solid (media powder)	≤30 min

References

1. Thermo Fisher Scientific (2021) Mixing efficiencies for the 2,000 L imPULSE Single-Use Mixer.
2. Thermo Fisher Scientific (2021) Hydration and scale-up of AGT medium in HyPerforma and imPULSE Single-Use Mixers.

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