



Single-use mixing technologies

HyPerforma and imPULSE single-use mixing systems for applications across the bioprocessing workflow



Proven mixing solutions for every budget and application

Thermo Scientific™ mixing products are designed for current good manufacturing practice (cGMP) bioprocessing applications, both upstream and downstream, and feature companion Thermo Scientific™ BioProcess Container (BPC) products designed specifically for superior performance in our systems. These products, whether standard or customized, deliver high value and dependability.

Two primary mixing technology platforms

- **Thermo Scientific™ HyPerforma™ Single-Use Mixer (S.U.M.)**—top-down stirred-tank design: available in sizes ranging from 50 L to 2,000 L and features the Touchscreen Console
- **Thermo Scientific™ imPULSE™ Single-Use Mixer (S.U.M.)**—proprietary bottom-mounted imPULSE technology design: available in sizes ranging from 30 L to 5,000 L

Multiple mixing formats

- **Thermo Scientific™ HyPerforma™ Single-Use Mixer DS 300**—available in plastic, in sizes ranging from 50 L to 300 L
- **Thermo Scientific™ HyPerforma™ Mixtainer™ system**—economical top-down stir-bar mixer for low-cost mixing: available in sizes ranging from 50 L to 200 L

HyPerforma Single-Use Mixer

Efficient and powerful mixing

The upgraded HyPerforma Single-Use Mixer (S.U.M.) has been enhanced to improve its functionality, ease of use, and ergonomics. Since the launch of the HyPerforma S.U.M. in 2006, we've maintained one of the largest install bases of mixing systems, which are in daily use by many global biopharmaceutical companies. Our customers appreciate the advanced engineering of the HyPerforma S.U.M.—the design of which is based on a traditional stirred-tank mixing system—as well as our ability to rapidly deliver BPC systems designed to their exact specifications.

Design enhancements

The HyPerforma S.U.M. is available in six sizes—50 L, 100 L, 200 L, 500 L, 1,000 L, and 2,000 L—and has a 5:1 mixing-volume turndown ratio. The effective mixing volumes range between 10 L and 2,000 L.

Features and benefits

- Touchscreen Console provides ease of use with multifunctional capabilities to monitor and control mixing parameters
- Cable management system for improved ease of use with BPC process lines for system organization
- Access door for convenient BPC loading on the 500 L, 1,000 L, and 2,000 L mixing systems
- Water-jacketed (heating) and non-jacketed (no heat transfer) options; improved high-flow water jacket with side and bottom jacket to improve system heat transfer
- Adjustable powder hanger that fits 1 kg, 5 kg, and 25 kg Thermo Scientific™ Powdertainer™ BPCs
- Two swivel-locking casters and push handles for better maneuverability of the units (except 2,000 L)
- BPC tab holders for easy single-use container setup
- Dual-probe opening for redundancy and low-volume pH and conductivity monitoring
- Open-cart frame for easy cleaning
- Touchscreen Console: IP 54 enclosure



Applications

- Media preparation
- Final formulation steps
- Buffer preparation
- Harvest vessels
- Large-volume mixing for up to 2,000 L
- Pooling and transfer
- Resuspension
- Mixing and storing multiple batches
- Harvest collection and bulk mixing
- Viral inactivation

HyPerforma S.U.M. specifications

Controllers and options

We offer integration with a variety of controller systems for the HyPerforma S.U.M. through our network of integration partners. Our open-architecture approach allows you to integrate with many controllers, potentially including one already in use in your facility. Additional options include a cable management system, pump shelving, storage basket, load cells, and powder arm assembly.

As an engineered-to-order product, the HyPerforma S.U.M. with Touchscreen Console can be fully integrated with either Thermo Scientific™ HyPerforma™ G3 Bioprocess Controllers, or controllers from other manufacturers—providing an open-architecture mixing solution configured to your unique requirements. The Touchscreen Console can integrate Thermo Scientific™ TruBio™ automation software powered by Emerson's DeltaV Distributed Control platform, enabling users to optimize data acquisition while maintaining full compliance with 21 CFR Part 11.

S.U.M. tank design

The stainless steel vessel of the HyPerforma S.U.M. is ergonomically designed, and has a compact footprint with the operator's ease of use in mind. With clear access to harvest lines, sight windows and level indicators, and a brushed stainless steel finish, the HyPerforma S.U.M. system can be utilized as a standard model, or customized to meet your specific process needs.

S.U.M. BioProcess Containers (BPCs)

Thermo Scientific BPCs are available for the HyPerforma S.U.M. in standard or customized configurations, with your choice of Thermo Scientific™ CX5-14 or Aegis™ 5-14 film. Thermo Scientific films have among the cleanest particulate profiles in the industry and are unsurpassed in their robustness, flexibility, and mechanical properties. Thermo Scientific BPCs can be used for pooling and storing material for your liquid-to-liquid and powder-to-liquid bioprocess mixing applications. BPC systems come in open- and closed-top designs. Custom BPCs can accommodate a range of applications. A variety of components have been qualified to maximize design flexibility, including:

- Single-use pH and pressure sensors
- A variety of tubing, clamps, and connector end treatments to facilitate your specific process



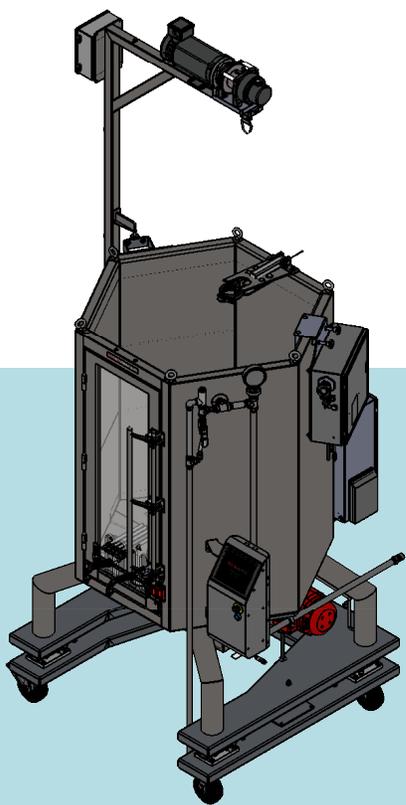
imPULSE Single-Use Mixer

The imPULSE Single-Use Mixer (S.U.M.) can be utilized for many bioprocess mixing applications. The imPULSE design features include innovative disc mixing technology, configurable high-end controls, and monitors to fit specific process requirements. These features all enable uniform, superior mixing—scalable from 30 L to 5,000 L.

The Touchscreen Console for the imPULSE S.U.M. provides superior integrated sensor monitoring, and pump control for pH and saline titration and for automatic fill and harvest of the S.U.M.

Efficient and customizable

The standard imPULSE mixing BPCs are made of Thermo Scientific™ ASI™ 26/77 polyethylene two-layer film. These BPCs are available with four inlet/outlet lines and a powder addition port. The standard tube sets connect to the imPULSE Mixing BPC for liquid addition, powder addition, recirculation, inflation, and vent control. The tube sets are modular and can be customized to best suit your process.



Standard features

- 304L stainless steel vessel and sliding window or door and window
- Clean room–grade stainless steel non-marring casters available on 30 L–1,000 L systems
- Rolling diaphragm
- Touchscreen Console: IP 54 enclosure

Key features

- Touchscreen Console provides ease of use with multifunctional capabilities to monitor and control mixing parameters
- Integrated rolling diaphragm that provides the pumping action to the mixing disc; the diaphragm will not abrade the surfaces or produce particulates
- Mixing tank jacket and insulation
- Weighing systems that utilize load cells enable accurate batch weight monitoring
- Auto inflate and vent control options
- Adjustable powder hanger for 1,000 L and higher mixers that fits 1, 5, and 25 kg Powdertainer BPCs
- Open cart frame for easier cleaning

Applications

- Media preparation
- Final formulation steps
- Buffer preparation
- Harvest vessels
- Large-volume mixing for up to 5,000 L
- Pooling and transfer
- Resuspension
- Mixing and storing multiple batches
- Viral inactivation

imPULSE mixing disc technology

Superior mixing in every model

The imPULSE mixing system provides superior mixing with configurable high-end controls and monitors to fit specific process requirements. Various options for instrumentation, powder bag handling, and a peristaltic pump are available to make a custom-tailored system for your process.

imPULSE mixing disc technology

The disc, an integrated part of the single-use BPC, is designed with slots and silicone flaps. The moving disc creates a pulsing action—the flaps open as the disc moves up from the bottom of the mixing BPC and fluid flows through the slots; the flaps close as the disc moves on the downstroke and energy is directed down and channeled through the space between the mixing disc profile and the vessel side walls. The velocity of the displaced liquid provides robust mixing.

A rolling diaphragm provides an interface between the BPC and the movable shaft with the mixing disc. There are no contact surfaces between the side walls and the diaphragm; therefore, the system does not generate particulates.

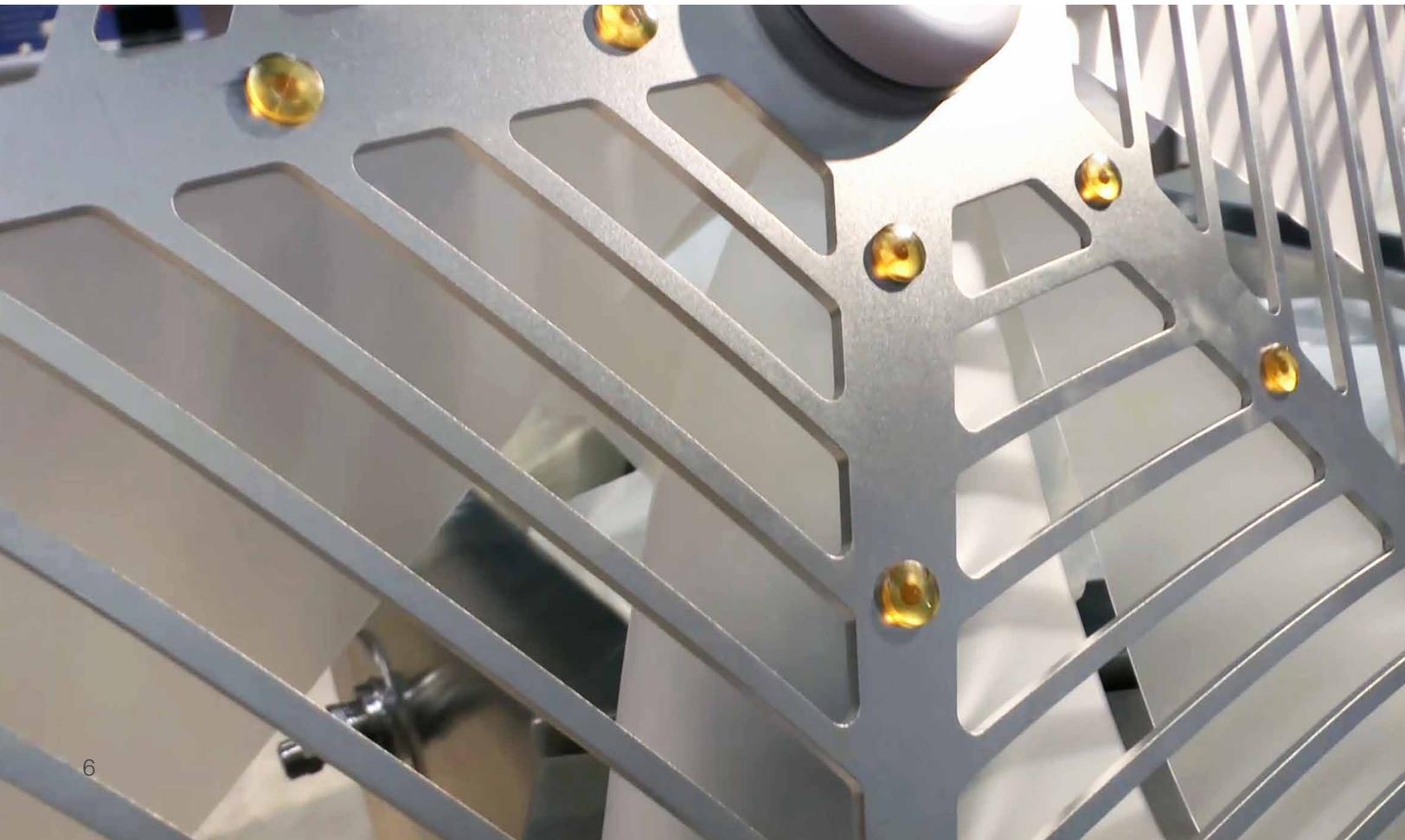
Linear scalability

The imPULSE mixing disc diameter increases proportionally as the size of the vessel increases. The ratio of the displaced liquid volume to the vessel volume is the same for all sizes, ranging from 30 L to 5,000 L. This enables consistent and reproducible results, as processes are seamlessly scaled up across all sizes.

imPULSE mixing disc features

In addition to the disc technology and linear scalability, the imPULSE S.U.M. has unique features that contribute to thorough mixing, product safety, and reproducibility.

- Speed is variable from 0 to 2 cycles per second; no vortex is created
- Mixes from full to empty, and suspensions are maintained down to empty



Touchscreen Console (TC)

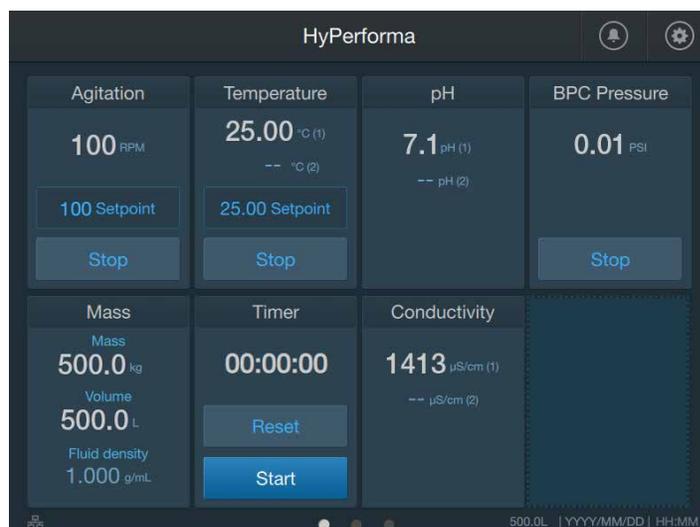
The Touchscreen Console provides state-of-the-art in-process monitoring and automation capability for the HyPerforma and imPULSE S.U.M.s. Its modular design allows for an easy-to-use custom user interface. Capabilities include: agitation, pumps, pinch valves, and temperature control. Users can easily visualize measurements from load cells, pH sensors, conductivity sensors, resistance temperature detectors (RTDs), and pressure sensors.

Key advantages

To suit various processes, the user is able to semi-automate their formulation, pH or saline titrations, and viral inactivation processes with the Touchscreen Console. Additionally, the system's modular design allows for an ergonomic, custom user interface. Simple, routine processes can be automated by utilizing measurement values to control the pumps, temperature control unit (TCU), and agitation motor. The data measured during a process can be exported remotely via Ethernet, Profibus, Modbus RTU, or using a USB drive.

Touchscreen Console module functionalities

The main screen is populated with user-selectable modules, which allow for simple screen customization.



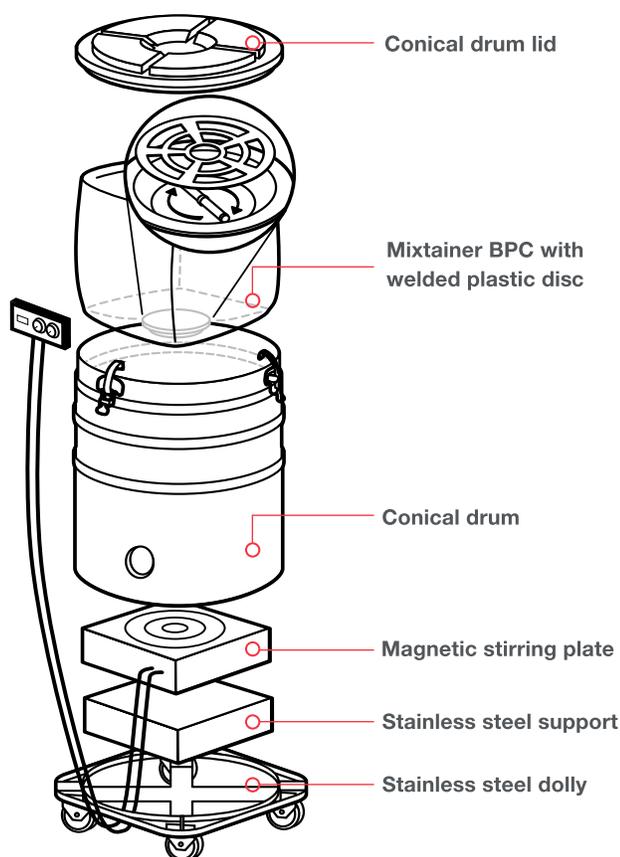
The interface above highlights the module functionalities for the HyPerforma S.U.M.

Modules	HyPerforma S.U.M.	imPULSE S.U.M.
Pump control	✓	✓
BPC pressure	✓	✓
Liquid pressure	✓	✓
Auxiliary output and input	✓	✓
Automated and metered fill and harvest	✓	✓
Agitation	✓	✓
Mass	✓	✓
Temperature	✓	✓
Timer	✓	✓
pH	✓	✓
Conductivity	✓	✓
Recipe function	✓	
PDC pressure		✓

Mixtainer system

The Mixtainer system is an integrated, single-use system for mixing cell culture media and process liquids such as buffers, reagents, and bulk drug precursors and products. The Mixtainer system utilizes a sophisticated BPC constructed with CX5-14 film, with a plastic disc welded into the base of the BPC. This disc contains a magnetic stir bar that is held in the operating position using a locking ring.

- Available in 50 L, 100 L, and 200 L volumes
- Standard BPCs available for liquid-to-liquid and powder-to-liquid mixing
- Supporting hardware optimized for mixing, storage, transport, and discharge in a closed system to help minimize the risk of cross-contamination



Mixtainer BPCs

Four ports, top dispense

- Line 1: 9.5 mm (0.38 in.) quick-connect insert with 16.5 cm (6.5 in.) dip tube; tube length: 91 cm (36 in.)
- Line 2: 6.3 mm (0.25 in.) Luer-lock insert; tube length: 91 cm (36 in.)
- Line 3: 6.3 mm (0.25 in.) Luer-lock body; tube length: 91 cm (36 in.)
- Line 4: 9.5 mm (0.38 in.) quick-connect body; tube length: 91 cm (36 in.)

Size	Cat. No.
50 L	SH30687.04
100 L	SH30687.05
200 L	SH30687.06

Mixtainer drum

Conical drum: top dispense, with clamps

Size	Cat. No.
50 L	SV50517.11
100 L	SV50517.12
200 L	SV50517.13

Mixtainer accessories

Description	Region	Cat. No.
Magnetic stirring plate (IKAMAG™ motor and support required) 230 V, 50/60 Hz, 0.5 A	EU	SV30097.01
Magnetic stirring plate (IKAMAG™ motor and support required) 115 V, 50/60 Hz, 1 A	US	SV30097.02
Stainless steel support	EU	SV30097.03
Stainless steel support	US	SV30097.04
Stainless steel dolly (D x H): 61.6 x 15.2 cm (24.3 x 6.0 in.)	Universal	SV50109.01

HyPerforma Single-Use Mixer DS 300

The HyPerforma S.U.M. DS 300 is based on the legacy design of our original S.U.M. and docking station—optimized for lower-cost, high-throughput applications. The smaller footprint, lighter weight, and more ergonomic design of the HyPerforma S.U.M. DS 300 provide system flexibility for a wide range of mixing applications.

Modular mixing for enhanced process efficiency

The HyPerforma S.U.M. DS 300 is a modular mixing station with features designed for simplicity and performance. The system utilizes a top-mounted mixing motor with an angular drive shaft. This industry-accepted design eliminates vortices, enables efficient mixing, and provides more power.

- **Mobility**—the ergonomically designed mixing station provides enhanced ease of use
- **Modularity**—choose from multiple drum sizes, mixing shafts, and mixing head heights to configure a modular solution for your bioprocessing applications
- **Interoperability**—specifically designed to combine mixing across multiple scales in one mixing station by attaching to drums of four different sizes (50 L, 100 L, 200 L, and 300 L)



The docking station consists of:

- Stainless steel base with locking casters
- Adjustable handle and handheld control device
- Electrical vertical lift mechanism with integrated height indicator
- Motor with motor mount to accommodate three drive shaft sizes
- Adjustable tools: spanner and torque wrench
- Adjustable-angle motor head and positioned drum are available as add-on options
- Top-drain support containers available in 50 L, 100 L, 200 L, and 300 L sizes; bottom-drain drums available in 50 L, 100 L, and 200 L sizes
- Top-drain tank liners available in all four sizes from 50 L to 300 L
- Tank liners available in three sizes from 50 L to 200 L, with bottom-access ports
- Closed-top 3D BPCs, with both top- and bottom-drain access ports, available in 50 L, 100 L, and 200 L sizes
- Optional dollies available for all drum sizes

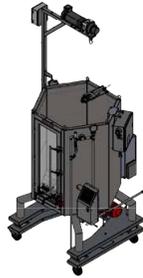
Applications

The S.U.M. DS 300 can be used in powder-to-liquid and liquid-to-liquid mixing applications. The top-mounted mixing design used in our HyPerforma S.U.M.s is used here to help ensure quality, and minimize the need for multiple mixers.

- **Hydration**—powdered media and buffers
- **Sterile mixing**—buffer solutions, cell culture media with sera and reagents, or other process fluids
- **Pooling**—sterile liquid fractions

Mixing platform comparisons

Each mixer comes with a comprehensive documentation package (user guide, equipment turnover package, validation guide) and is backed by our experienced team of technical support and field application specialists.



Mixer model	imPULSE S.U.M.	HyPerforma S.U.M.	HyPerforma S.U.M. DS 300	Mixtainer system
Description	Mixing—high control	Mixing—high control	Mix and dock	Mix, dock, ship
Size range (L)	30 L, 100 L, 250 L, 500 L, 1,000 L, 2,000 L, 3,000 L, 5,000 L	50 L, 100 L, 200 L, 500 L, 1,000 L, 2,000 L	50 L, 100 L, 200 L, 300 L	50 L, 100 L, 200 L
Linear scalability	Yes	Yes	Yes	Yes
Tank temperature control	Jacket heat	Jacket heat	No	No
BPC auto inflation and auto vent control	Yes	No	No	No
Sensors	pH, DO, CO ₂ , temperature, weight, conductivity, BPC pressure, liquid pressure	pH and conductivity, temperature, weight, BPC pressure, liquid pressure	No	No
Base mobility	Fixed/casters	Fixed/casters	Casters	Casters
Mixing technology	Bottom: imPULSE	Top: stir tank	Top: stir tank	Bottom: stir bar
Controls	Touchscreen Console (e-box)	Touchscreen Console (e-box)	Handheld controls	Power, speed
Minimum mixing volume	1%	20%	20%	1%
Drain location	Bottom	Bottom	Bottom	Top
Particulate generation	None	None	None	Medium
Services and support*	Yes	Yes	Yes	Yes
Fluid vortex	No	No	No	No
Tank materials	Stainless steel	Stainless steel	Plastic	Plastic
Sparge capable	Yes	Yes	No	No
Minimum ceiling height requirements	30–2,000 L: 8 ft 3,000 L: 9 ft 5,000 L: 10.5 ft (without crane)	50 L, 200 L: 8 ft 500 L, 1,000 L: 9 ft 2,000 L: 10 ft	50 L–300 L: 8 ft	<8 ft

* Options include factory acceptance test (FAT), site acceptance test (SAT), installation and operational qualification (IQ), planned maintenance (PM), instrument service, and validation support.

Services and support solutions

Risk mitigation to protect your single-use processes

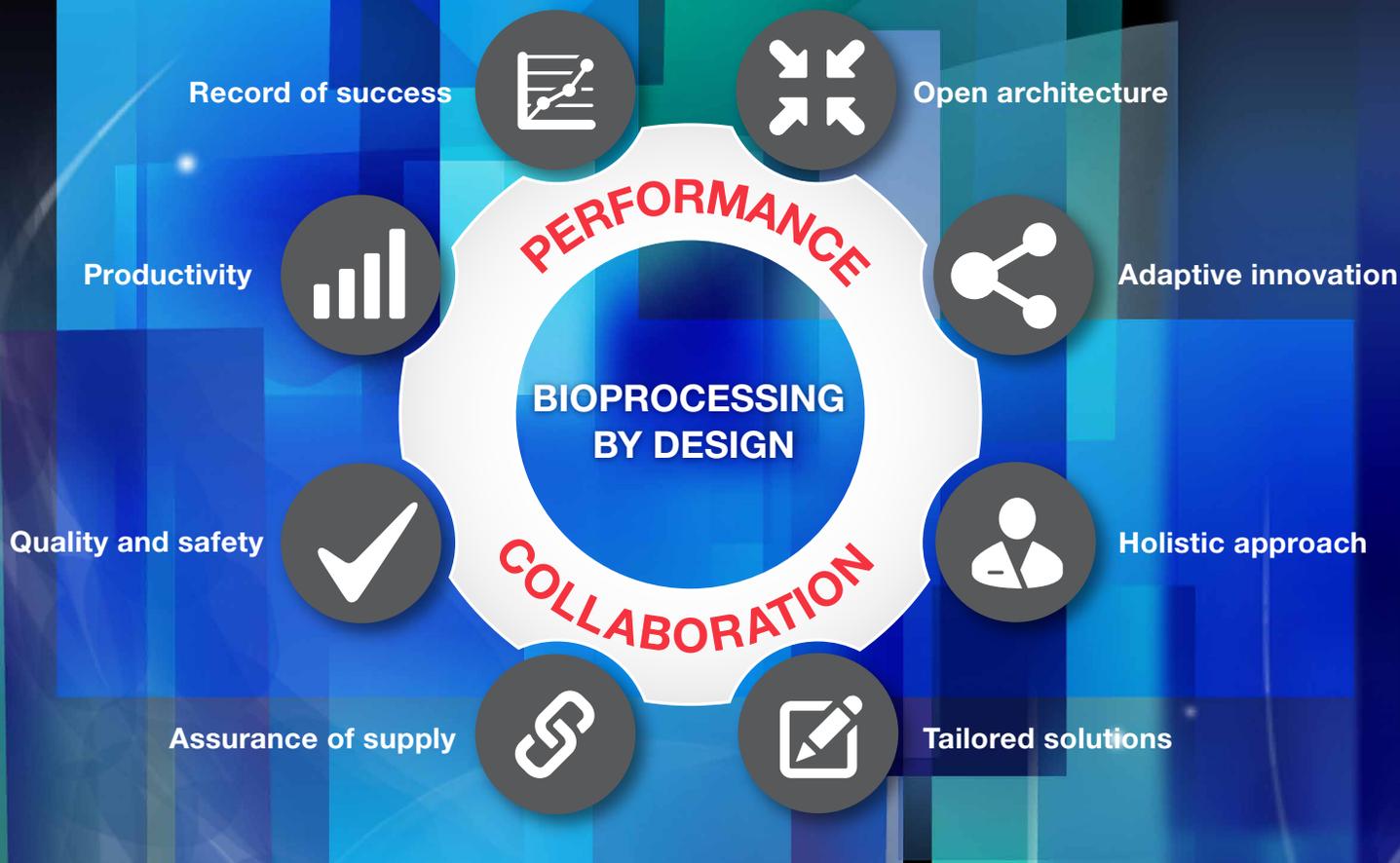
Engage with our specialists who can provide a wide range of services to support the investment in your processes using Thermo Scientific single-use products. We work in close collaboration with you to help ensure your operational needs are met. These services include:

- Preventive maintenance plans*
- Qualification and commissioning for HyPerforma and imPULSE S.U.M.s
- Technical support services, such as optimization audits that include process workflow and optimization evaluations
- Custom development services for flexible containers, including fluid transfer assemblies
- Process development services at our Customer Experience Center in Logan, Utah

While most of our customers enjoy the benefits of using our services in conjunction with our single-use technology, we invite you to learn more about each individual service component by speaking with a sales representative.



* Qualification and commissioning (FAT/SAT/IOQ) or preventive maintenance on the Mixtainer system is not available at this time.



Bioprocessing by Design

Driving performance through collaboration

To meet the increasing demand for biologics worldwide, you need to expect more from suppliers. It isn't just about the products we deliver, but how we do business together.

With a collaborative approach that is grounded in our technical knowledge, we work with you to achieve optimal bioprocessing outcomes. Committed to identifying the technologies and services that address your needs, from drug development through large-scale commercial production, we provide integrated and tailored solutions that improve the overall biomanufacturing experience. If a solution doesn't exist, we'll build it—together.

And while we are flexible in our approach, we are uncompromising in our pursuit of performance. Through technical engagement, innovative product design, and strategic sourcing programs, we deliver productivity, quality, and assurance of supply so that you can have confidence in the efficiency and speed of your biologics development and manufacturing processes.

That's our commitment to you, and it's what we call Bioprocessing by Design.

Find out more at thermofisher.com/bioprocessing

ThermoFisher
SCIENTIFIC

For Research Use or Further Manufacturing. Not for diagnostic use or direct administration into humans or animals.
© 2020 Thermo Fisher Scientific Inc. All rights reserved. All trademarks are the property of Thermo Fisher Scientific and its subsidiaries unless otherwise specified. DeltaV is a trademark of Emerson. IKAMAG is a trademark of IKA Works. COL012100 0820