BETTER BUFFER MANAGEMENT

DATA SPECIFICATION SHEET

MULTIPLE CONTROL OPTIONS

INLINE BUFFER FORMULATION



INLINE BUFFER FORMULATION (IBF) SYSTEMS

Buffer management in the biopharmaceutical industry has been a steady state for decades, without much in the way of innovation. Buffers are traditionally made at the formulation required by each unique process and, depending on scale, can require significant investment in preparation capacity, storage capacity, facility footprint, and personnel to continuously replenish supply. As next generation biopharma processes have significantly increased yield in upstream manufacturing over the last several years, the burden placed on downstream buffer production capacity has increased dramatically.

Enter MOTIV® Inline Buffer Formulation (IBF™) – the solution to this growing problem, and a step change in the industry for buffer production. Most biopharma processes use common base chemicals throughout the process but at different molarity or pH targets. The versatility of IBF allows for multiple control options based on each unique process design. MOTIV systems allow for:

- ➤ Highly concentrated single chemical stock solutions that can be blended in precise proportions to formulate on demand (most appropriate for chemicals common throughout the DSP process).
- > Highly concentrated formulated stock solution that is inline diluted with WFI (most appropriate for chemicals unique to a single process step, such as final TFF diafiltration).
- > Formulated buffer temperature control prior to entering process analytic technology (e.g., pH and conductivity) improving measurement precision.
- Adjustment of individual stock solutions input based on real time pH and/or conductivity feedback to target a precise setpoint.
- **>** Buffer formulation control using feedback loop for pH, conductivity, and flowrate.
- > Formulation to a break tank, BPC or directly to the process (e.g., chromatography or TFF).
- Rapid stabilization maintained throughout formulation (system will divert to drain at start-up until process control is stable for a configurable amount of time).









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When MOTIV is applied to maximize efficiency, the following can be gained:

- > Significant reduction in the volume of stock solutions per batch resulting in ability to produce multiple batches from the same stock solution.
- > Significant reduction in the size and number of buffer preparation vessels.
- **>** Elimination of buffer storage capacity if formulating directly to the process.
- > Reduction in facility footprint required to house buffer equipment/solutions.
- Reduction in buffer schedule which translates to fewer resources required to maintain buffer supply.
- > Significant reduction in plastic waste depending on how system is applied.



MOTIV Inline Buffer Formulation systems are deployed in commercial scale settings where it has proven to facilitate 2x - 4x increase in protein purification using 50% of the facility footprint in the same amount of time as a facility with traditional capabilities. Its versatile formulation and configuration capacities can suit any process need whether it's a limited single product use or a high throughput multi-product facility.

Creating safe, affordable biologics today requires increased buffer production. Asahi Kasei Bioprocess is dedicated to unlocking efficiencies and driving buffer productivity in your biopharmaceutical downstream processing area. You can move beyond downstream bottlenecks with MOTIV®: our line of industry-leading inline buffer formulation systems available in standard and custom configurations to give you confidence in achieving a consistent, precise yield every time.

ACCURATE AND REPRODUCIBLE BUFFER FORMULATION

Our IBF™ systems are trusted for cost-effective just-in-time preparation of millions of liters of dilute and pH-conditioned buffers from up to 20X stock concentrates in cGMP production facilities around the world.

PATENTED RECIRCULATION BLENDER TECHNOLOGY

Our patented dynamic recirculation blender built into every stainless-steel MOTIV™ dramatically improves the buffer response rate, allowing all systems to reach their target setpoints within seconds. Featuring highly efficient mixing regardless of flow rate or viscosity, increased pH adjustment precision, faster setpoint achievement and smaller washout volumes.

MAKING THE COMPLEX SIMPLE

Each of our inline buffer formulation systems can produce complex buffers constructed from various streams – providing the ultimate flexibility to generate mixtures using a combination of conductivity, pH and mass flow control. OCELOT® System Control will automate the process to ensure accuracy and repeatability.

INDUSTRY-LEADING BUFFER CAPABILITIES

MOTIV systems have been used to produce the widest range of buffers of any comparable system on the market – and can also handle high viscosity fluids, such as glycerol. In minutes, a 20X dilution of 100% glycerol was successfully performed at room temperature on a MOTIV 310 under both low flow (180 L/h) and high flow (1000 L/h) conditions.

TECHNICAL SPECIFICATIONS

Process specifications

Equipment	Specification
Functionality	Inline buffer formulation
Pump configuration	3-pump or 5-pump
Pump flow rate range	2MOTIV 3/510 (console): 60 – 1000 L/h MOTIV 3/512 (skid): 120 – 1200 L/h MOTIV 3/520 (skid): 200 – 2000 L/h MOTIV 3/550 (skid): 500 – 5000 L/h
Number of inlets	MOTIV 310: 3/bank MOTIV 510: 6/bank
Number of outlets	6
Process temperature	19°C to 28°C
Process pressure	0 to 3 barg
Environmental temperature	15°C to 30°C
Area classification (local to equipment)	Standard: Non-Hazardous Optional: Class1 Div2/ATEX Zone 2

System specifications

Equipment	Specification
	MOTIV 310/12: 770mm x 1500mm x 1610mm
	MOTIV 325: 1370mm x 762mm x 1854mm
Dimensions (standard W v D v H)	MOTIV 350: 1990mm x 1220mm x 1880mm
Dimensions (standard W x D x H)	MOTIV 510/12: 1530 mm x 1070mm x 1830mm
	MOTIV 525: 1800 mm x 762mm x 1854mm
	MOTIV 550: Custom build, inquire with sales rep
Weight	300-500 Kg based on options and pumps
Floor clearance	5.5"
Materials of construction (MOC)	316L SS
Surface finish	20 Ra + EP Product Contact
Protection rating	IP 66

UTILITY SPECIFICATIONS

Equipment	Specification
Electrical	400 VAC, 50 Hz (European), 460 VAC, 60 Hz (North American)
Voltage control	24 VDC, 20 A
Ingress protection (elec. cabinets)	IP 66 (European), NEMA 4X (North American)
Amperage	10 A
Motor power	0.75 kW (Mixer)
Air supply	6 bar 8 SCFM peak, 1 SCFM average







COMPONENT SPECIFICATIONS

Process equipment	Туре	Specification
Pump (concentrate/WFI)	QuattroFlow	Quattroflow 1200-S
Pumps (concentrate)	QuattroFlow	QF15DISPP-3-EZ
Flow meter	Endress + Hauser	Coriolis Meter (8BE08- C9999AAB41A3 8F1B08-6LH2/0)
Analytical Meter/ transmitter	Optek	Optek 8000
Conductivity/temperature probe	Optek	ACF60-35-18
pH probe	Broadley James	F-285
Back pressure regulator	Steriflow	MK95-100-HC22
WFI inlet management (valve)	Steriflow	MK96-075-6L
Filter inlet valve	Asahi America Dymatrix	MPV50-34 3/4" TC

AUTOMATION SPECIFICATION

Each MOTIV is outfitted with the latest in system control software – OCELOT® – bringing intuitive configuration to all inline buffer formulation process steps. In a universally compatible format, OCELOT can integrate and/or interface with your plant-wide control system, allowing for far-reaching data collection and analysis.

SPECIALIZED

- **>** Each system is built to manage your critical process conditions.
- > Settings, helper text and key process parameters can all be customized to create a unique user experience.
- > Designed to be simple and straightforward.

SEAMLESS INTEGRATION

- > OPC-ready architecture plugs into your existing DCS, OPC Server or Historian for batch monitoring and control.
- > Browser-based to allow remote method configuration and review of batches, even while the system is in use.

FLEXIBLE YET REPEATABLE

- > Recipe configuration, report templates and trend displays allow daily customization of system operations.
- > Default parameters, favorite steps, chart presets and report templates allow for easy repeat use.
- > Point-of-use scale-up/scale-down through Control Parameter functionality.









AUTOMATION HARDWARE SPECIFICATIONS

Process specifications

Equipment	Specification
PLC vendor	Rockwell/Allen Bradley
PLC model	5069 L320ER
PLC software	Studio 5000
Database	SQL
Operating system	Windows 10
Batch engine	OCELOT System Control
Historian	GE Historian
Reporting	OCELOT System Control
НМІ	Factory talk View SE
Panel PC	Advantech
UPS	N/A
Remote I/O	N/A
Ethernet switches	AB Starix 2000
OPC server	Factorytalk Linx Gateway

ORDERING INFORMATION

System hardware and accessories

Equipment	Specification
MOTIV 310	IBF-310
MOTIV 312	IBF-312
MOTIV 325	IBF-325
MOTIV 350	IBF-350
MOTIV 510	IBF-510
MOTIV 512	IBF-512
MOTIV 525	IBF-525
MOTIV 550	IBF-550
MOTIVplus	IBF-[# pumps][L/h]+

Support

A reliable technical support network is available throughout North and South America, Europe, and Asia.

Technical Client Services (TCS) is a customer-centric interface to our product and science experts. Our TCS team will guide your process and engineering needs as your personal liaison for inquiries.

> Parts and Consumables

Quality replacement parts are essential to ensuring high-performance of your equipment – and production continuity.





Training

Our dedication to providing the best in customer support is about more than just keeping your systems and columns up-and-running – our service extends to making sure your operators know how to use and maintain the installed equipment.

Maintenance

Ensure trouble-free operation of your equipment for years with a maintenance plan created to meet your specific needs.

Whatever your requirements, we work with you to configure the right plan, schedule, and pricing.

We offer an extendable 1-year warranty, service contracts and a personalized level of service for peace of mind and timely support when you need it.

