

HyPerforma 5:1 2,000 L Single-Use Bioreactor

Introduction

The Thermo Scientific™ HyPerforma™ Single-Use Bioreactor (S.U.B.) provides state-of-the-art functionality, ease of use, and efficiency. The complete HyPerforma S.U.B. system consists of a bioreactor tank and HyPerforma S.U.B. BioProcess Container (BPC), which is available in 50, 100, 250, 500, 1,000, and 2,000 L sizes with a 5:1 turndown ratio. The redesigned HyPerforma S.U.B. maintains traditional stirred-tank bioreactor design principles, including specific height-to-diameter ratios and an optimized mixer location that delivers optimum cell viability, performance, and scalability from process development through production. Design is optimized for the 2,000 L bioreactor tank, which allows for mixing at a 5:1 turndown ratio. Advantages of the 5:1 system include:

- Streamlining bioprocesses by reducing seed vessel requirements and maximizing process vessel usage
- Seeding vessels at 20% volume then feeding up to full volume
- Reducing cell transfers and associated adaptation
- Reducing the number of single-use BPCs used
- Adjusting the impeller position for a 2:1 or 5:1 turndown ratio

This data sheet provides information on the HyPerforma 5:1 2,000 L S.U.B. system, which includes the tank and standard S.U.B. BPC. The BPC utilizes a dual-sparger design with a drilled-hole sparger for cultures at nominal volume, and a cross-flow sparger strategically positioned just above the 20% liquid volume for seed cultures. The proprietary cross-flow sparger supports efficient cell culture at a lower volume. Both sparge designs have been rigorously tested to provide high $k_L a$ values and optimal CO_2 stripping for improved pH control and decreased foaming.



The HyPerforma 5:1 S.U.B. system consists of the following components:

- S.U.B. hardware unit available in turnkey format
- Complete mixing system with water jacket
- Driveshaft, which inserts into the S.U.B. BPC through the mixing drive motor and locks into the BPC agitator assembly
- Load cells

S.U.B. BPC (gamma-irradiated and ready to use)

- Agitator assembly is a single-use (polyethylene) impeller with a bearing-and-seal assembly linked to an external mixer drive
- Dual gas spargers available with cross-flow and drilled-hole design
- Vent filter outlet for system exhaust
- Integrally sealed ports in the S.U.B. BPC allow for additional sensor probes and line sets
- Available in Thermo Scientific™ CX5-14 Film and Aegis™ 5-14 Film options

System options (adaptable to your needs)

- Optional electrical box for remote agitation control
 - HyPerforma 5:1 S.U.B.s require a separate external temperature control unit
- Optional condenser system
- Exhaust gas vent filter heaters
- Load cell displays
- Process control system

- See the ordering information section for auxiliary components for S.U.B. control management. Choose an open architecture approach or a turnkey, “ready-to-use” HyPerforma S.U.B. system

Standard HyPerforma 5:1 S.U.B. hardware units

The 2,000 L standard 5:1 S.U.B. hardware units are available in the configurations below.

- 2,000 L jacketed S.U.B. with a 5:1 turndown ratio, AC motor, no E-box, and load cells without display
- 2,000 L jacketed S.U.B. with a 5:1 turndown ratio, AC motor, 240 VAC, E-box, and analog load cells

Table 1. 2,000 L standard 5:1 S.U.B. hardware unit with casters (leveling feet).

Description	Cat. No.
2,000 L jacketed S.U.B. with a 5:1 turndown ratio, AC motor, no E-box, 2-piece driveshaft, single 120 in. Bulgín RTD, and load cells with no display	SUB2000.9009
2,000 L jacketed S.U.B. with a 5:1 turndown ratio, AC motor, 240 VAC, E-box, 2-piece driveshaft, single 120 in. Bulgín RTD, and analog load cells	SUB2000.9010

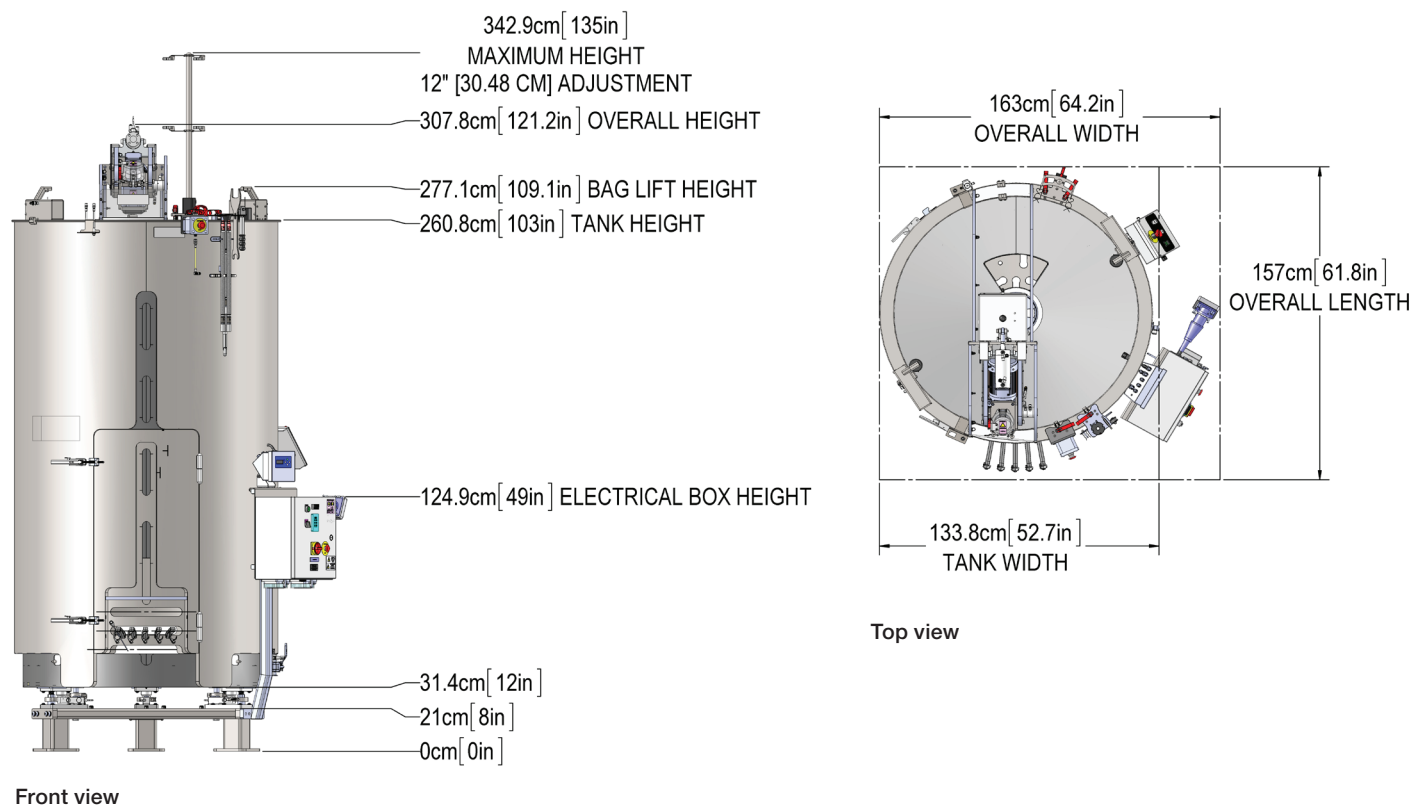
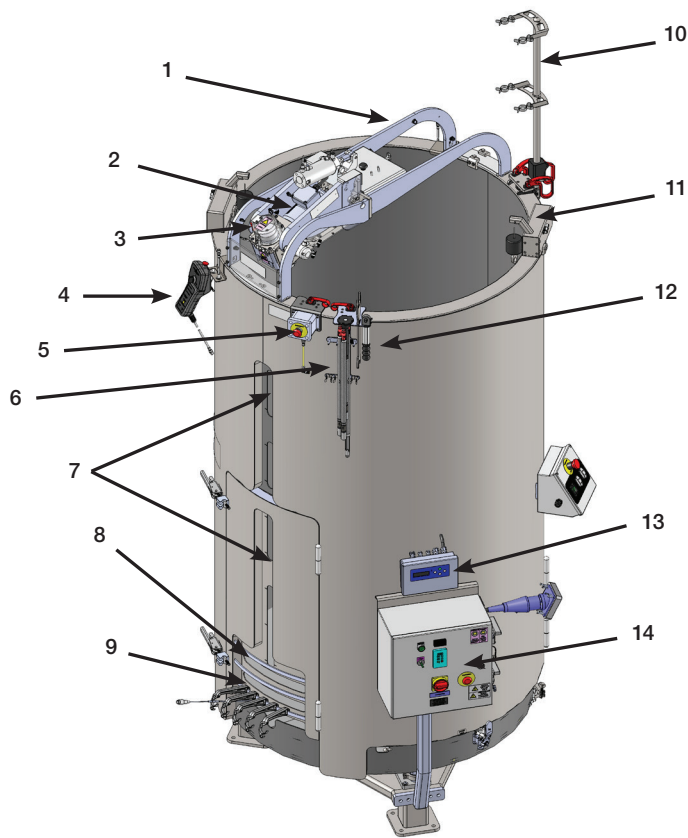


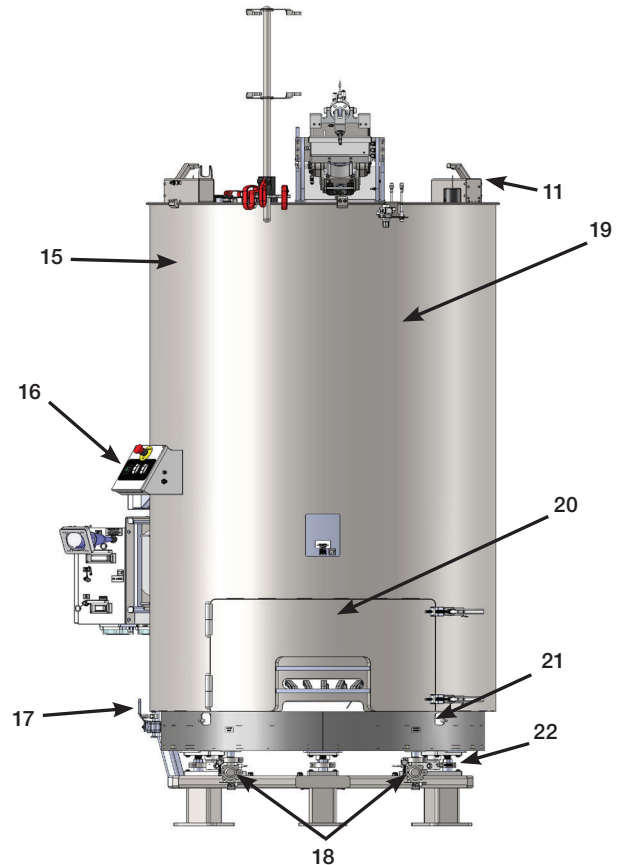
Figure 1. 2,000 L 5:1 S.U.B. hardware unit dimensions.

Design features

1. Motor lift
2. Mixer motor
3. Mixing assembly with motor safety shield
4. Handheld controller for motor adjustment (on bracket)
5. Emergency E-stop
6. Driveshaft (stored)
7. Liquid sight windows
8. Probe access window
9. Probe hanger bracket (with probe clips)
10. Exhaust vent filter holder
11. BPC lift (2)
12. Standard tool set: 3/8 in. x 150 in.-lb square torque wrench, load cell, and motor cap lockout wrench
13. Load cell display
14. Electrical control panel (optional)
15. 3/8 in. dimpled jacket (side)
16. BPC lift control
17. Bleed valve
18. Quick connect water inlet/outlet ports
19. Stainless steel (304) outer support container
20. Rear access door
21. Bottom cutouts/pins for BPC attachment/alignment
22. Load cell (3)



Front view



Back view

Figure 2. 2,000 L 5:1 S.U.B. hardware unit.

Table 2. 2,000 L standard 5:1 S.U.B. system specifications.

		AC motor
Bioreactor geometry	Rated liquid working volume	2,000 L
	Minimum liquid working volume (5:1 operation)	400 L
	Total reactor volume (liquid and gas)	2,575 L
	BPC chamber diameter	119.4 cm (47 in.)
	BPC chamber shoulder height	229.9 cm (90.5 in.)
	Liquid height at rated working volume	178.7 cm (70.35 in.)
	Fluid geometry at working volume (height:diameter ratio)	1.5:1
	Overall reactor geometry (height:diameter ratio)	1.9:1
	Tank baffles	No
General	Ceiling height required for 2-piece driveshaft loading	381 cm (150 in.)
	Ceiling height required for 4-piece driveshaft loading	353.06 cm (139 in.)
	Electrical power supply requirement (voltage, phase, current)	208–240 VAC, single, 30 A (dependent on controller)
	pH and DO probe, autoclavable type	12 mm diameter x 215–235 mm insertion length x 13.5 PG (pipe) thread
	Noise level	< 70 dB at 1.5 m
Impeller	Impeller (quantity x blade count)	1x3
	Impeller scaling (impeller diameter/tank diameter)	1/3
	Impeller blade pitch (angle)	45°
	Impeller diameter	39.7 cm (15.67 in.)
	Impeller-calculated power number (N)	2.1
Agitation	Agitation speed range (5:1 operation)	Standard operation: 20–75 rpm
	Nominal agitation rating (power/volume)	20 W/m ³
	Nominal agitation, 20% working volume (5:1 operation)	44 rpm
	Nominal agitation, 50% working volume	60 rpm
	Nominal agitation, 100% working volume	75 rpm
	Nominal tip speed	154.9 cm/s (305 ft/min)
	Counterclockwise mixing flow direction	Down-pumping
	Agitation shaft resolved angle (5:1 operation)	16.6°
	Agitation shaft centerline offset	6.7 cm (2.63 in.)
	Overall driveshaft length	215.5 cm (84.9 in.)
	Driveshaft diameter	1.91 cm (0.75 in.)
	Driveshaft poly-sheath outside diameter	3.51 cm (1.38 in.)
	Impeller clearance from tank bottom (5:1 operation)	13.9 cm (5.49 in.)
Minimum acceleration and deceleration rate	60 seconds	

Table 2. 2,000 L standard 5:1 S.U.B. system specifications (continued).

		AC motor
Motor	Agitation motor drive (type, voltage, phase), AC motor only	Induction, 208 VAC, 3
	Motor power rating (AC motor)	372.8 W (0.5 hp)
	Motor torque rating	27.7 N-m (245 in.-lb)
	Gear reduction	15:1
	Programmable VFD, remote panel interface, power fault auto restart	Standard
	Motor communication methods (for external controller)	0–10 V; 4–20 mA; Modbus
Temperature control	Jacket area: full/half volume	4.54 m ² (48.9 ft ²)/2.47 m ² (26.6 ft ²)
	Jacket volume	44 L
	Jacket flow rate at 3.4 bar (50 psi)	75 L/min
	Process connection	1.5 in. sanitary tri-clamp
	Nominal heating/cooling load (W)	18,000 W
	Approximate liquid heat-up time (5–37°C), 20% volume	1.4 hr
	Approximate liquid heat-up time (5–37°C), 100% volume	4 hr
	RTD or thermocouple, 3.18 mm (1/8 in.) OD	RTD: Pt-100 (standard)
Support container	Overall width	179.7 cm (70.5 in.) with E-Box
	Overall length	171.4 cm (67.5 in.)
	Overall height	321.1 cm (126.4 in.)
	Dry skid weight (mass)	962.1 kg (2,121 lb)
	Wet skid weight, rated working volume (mass)	2,962.1 kg (6,530 lb)
Recommended operating parameters	Operating temperature range	Ambient to 40 ± 0.1°C (104 ± 0.2°F)
	Motor speed	Standard operation: 20–75 rpm, working volumes must stay above 50% during agitation
	Volume range	400–2,000 L
	Maximum BPC pressure	0.03 bar (0.5 psi)
Motor lift	Power supply requirements	24 VDC, 90 psi of air
	Weight	126.1 kg (278 lb)
BPC lift	Electrical power supply requirements	120–240 VAC, 50/60 Hz, 10 A
	Duty cycle for motor	Tested to 5 cycles/ten minutes

System options

Table 3 lists available S.U.B. system options for the 2,000 L size.

- **Sparge line support** (Figure 3)—keeps gas lines in an upright position for optimal gas transfer.
- **Heavy-duty tubing clamp** (Figure 4)—used for each probe port not in use and eliminating process fluid holdup.
- **Autoclave tray for probe kits** (Figure 5)—aids in holding the probe assembly during the autoclave process.
- **Additional information on autoclave tray:**
 - Fabricated from stainless steel
 - Plastic carry handle for easy transport right out of the autoclave
 - Positions probes on 15% incline for greater probe/membrane longevity
 - Will restrain probe bellows from collapsing during sterilization
 - Probe holder accommodates two probes
- **Condenser system** (Figures 6 and 7)—available side-mounted or with cart assembly.
- **Mobile stairs** (Figure 8)—facilitates access to the bioreactor for top-mount driveshaft loading. The 2,000 L S.U.B. requires a platform for top-mount driveshaft loading. Customer may provide their own solution.
- **S.U.B. temperature sample port** (Figure 9)—provides off-line temperature probe calibration prior to system start-up.
- **Bioreactor probe assembly** (Figure 10)—required for each sterile electrochemical probe insertion.
- **Sterile sampling manifolds**—available in 50 and 100 mL sizes for off-line sample retention.

Table 3. 2,000 L standard 5:1 S.U.B. system options.

Description	Cat. No.
Complete condenser system (120 V) including cart, chill plate, and mounting post with filter brackets, TCU, and pump	SV50232.01
Complete condenser system (240 V) including cart, chill plate, and mounting post with filter brackets, TCU, and pump	SV50232.02
Autoclave tray	SV50177.01
Bioreactor probe assembly with CPC AseptiQuik™ connector (nonsterile for use in autoclave)	SH30720.02
Sparge line support	SV50177.65
Heavy-duty tubing clamp (each)	SV20664.01
Heavy-duty tubing clamp (10 per pack)	SV20664.04
Sterile sampling manifold with Luer lock (each)	SH30845.01
Sterile sampling manifold with Luer lock (10 per pack)	SH30845.02
S.U.B. temperature/sample port	SV20750.01
Tubing assembly with PendoTECH pressure sensor	SH31134.01
Tubing assembly with Finesse™ pressure sensor	SH31134.02
Mobile stairs	SV50935.01



Figure 3. Sparge line support.



Figure 4. Heavy-duty tubing clamp.

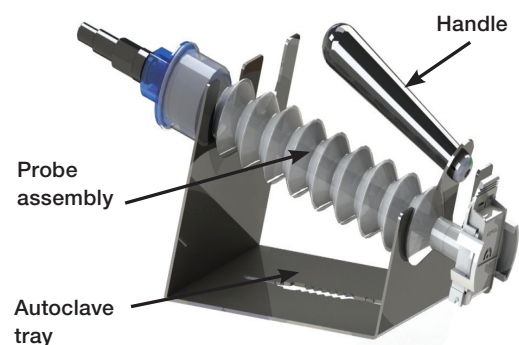


Figure 5. Autoclave tray for probe kits.

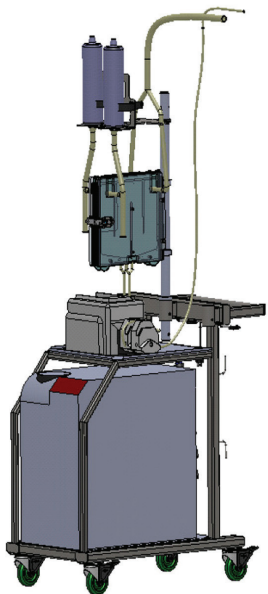


Figure 6. Condenser system with cart.

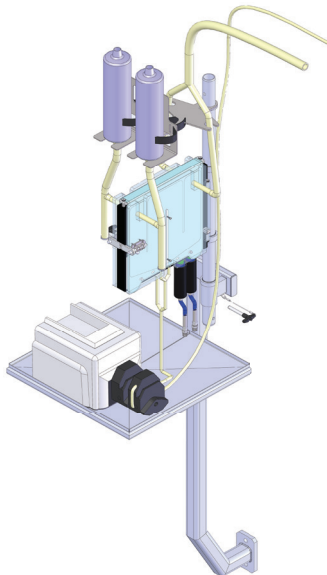


Figure 7. Side-mounted condenser system.



Figure 8. Mobile stairs.



Figure 9. Temperature sample port.



Figure 10. Bioreactor probe assembly.

Vent heaters

Vent heaters aid in reducing moisture buildup in exhaust filters from system off-gassing. Vent heaters are factory preset at 50°C, allowing for condensation to return to the vessel. Recommended gassing strategies of the S.U.B. system are in the 5:1 S.U.B. Validation Guide DOC0023. Table 4 lists available vent heaters. **Note:** Vent heater is not required if the condenser system is purchased.

Table 4. Vent heater required for each exhaust filter on S.U.B. BPC.

Description	Cat. No.
120 VAC, 99.6 W, Meissner™ 10 in. series 46 vent filter heater, preset temperature bulb, IEC 320 C14	SV50191.33
240 VAC, 99.6 W, Meissner 10 in. series 46 vent filter heater, preset temperature bulb, IEC 320 C14	SV50191.34
120 VAC, 99.6 W, Meissner 10 in. series 46 vent filter heater, integrated, M12-4 pin connector*	SV50191.47
240 VAC, 99.6 W, Meissner 10 in. series 46 vent filter heater, integrated, M12-4 pin connector*	SV50191.48
120 VAC, 23.8 W, Pall™ Kleenpak™ KA3 series 46 vent filter heater, preset temperature bulb, IEC 320 C14	SV50191.31
240 VAC, 30.3 W, Pall Kleenpak KA3 series 46 vent filter heater, preset temperature bulb, IEC 320 C14	SV50191.32
120 VAC, 23.8 W, Pall Kleenpak KA3 series 46 vent filter heater, integrated, M12-4 pin connector*	SV50191.45
240 VAC, 30.3 W, Pall Kleenpak KA3 series 46 vent filter heater, integrated, M12-4 pin connector*	SV50191.46

* Require integration to a third party controller, which allows vent heater control through system HMI.

Harsh mount load cell display

Required for remote weight readout from Mettler-Toledo's summing box; various signal output options are provided for external control monitoring (Table 5). More information can be found in the Load Cell Data Sheet.



Figure 10. Harsh mount load cell display.

Spare parts

Table 6 lists the available spare parts of the 2,000 L S.U.B. systems. Spare parts are for standard reference only; configured S.U.B. tank drawings will be provided with a spare parts list specific to the S.U.B. tank ordered.

Table 5. Harsh mount load cell display options.

Description	Cat. No.
Mettler-Toledo™ IND331 display, with analog interface (STD), 120 VAC U.S. line cord/plug	SV50177.306
Mettler-Toledo IND331 display, with Allen-Bradley RIO interface, 120 VAC U.S. line cord/plug	SV50177.307
Mettler-Toledo IND331 display, with DeviceNet interface, 120 VAC U.S. line cord/plug	SV50177.308
Mettler-Toledo IND331 display, with ethernet/IP and Modbus TCP interface, 120 VAC U.S. line cord/plug	SV50177.309
Mettler-Toledo IND331 display, with Profibus interface, 120 VAC U.S. line cord/plug	SV50177.310

Table 6. Available spare parts.

Description	Cat. No.
AC motor	SV50237.19
2-piece carbon fiber driveshaft	SV50959.21
4-piece carbon fiber driveshaft	SV50959.20
RTD 304.8 cm (120 in.) with Bulgin connector	SV50177.363
Probe holders	SV50177.23
Probe kit autoclave (stainless steel with plastic carry handle)	SV50177.01
Adjustable filter bracket	SV50177.313

Table 7. 2,000 L standard 5:1 S.U.B. BPC packaging.

Outer packaging	Supplied “flat-packed” Two polyethylene outer layers
Label	Description Product code Lot number Expiry date on outer packaging and shipping container
Sterilization	Irradiation (25 to 40 kGy) inside outer packaging
Shipping container	Durable cardboard carton
Documentation	Certificate of Analysis provided with each lot for delivery

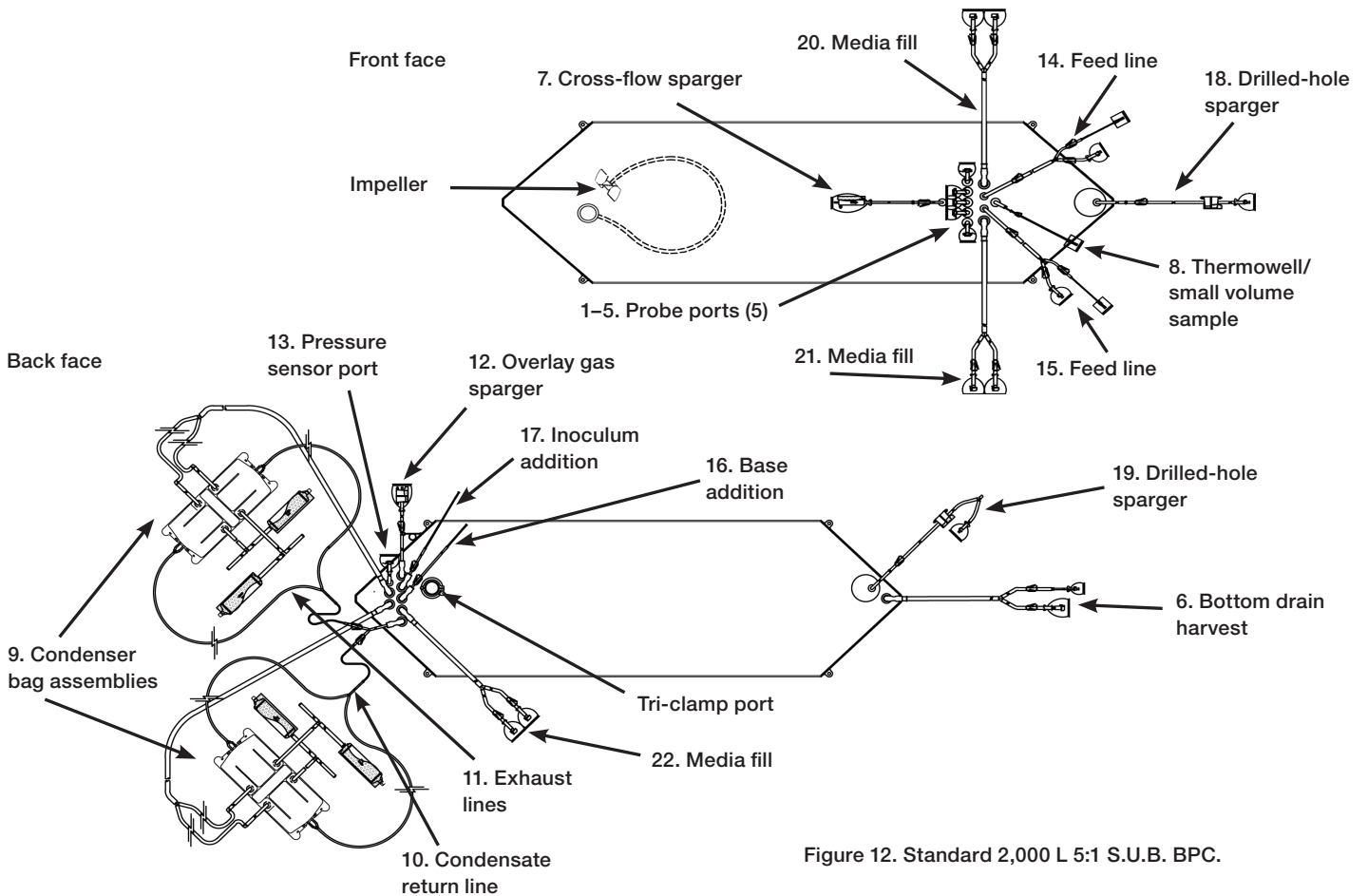


Figure 12. Standard 2,000 L 5:1 S.U.B. BPC.

Standard 2,000 L dual-sparger S.U.B. BPC systems

Standard S.U.B. BPC packaging is shown in Table 7. Table 8 shows the available standard 2,000 L S.U.B. BPC system options with drilled-hole and cross-flow spargers.

Table 8. 2,000 L standard 5:1 dual-sparger S.U.B. BPCs.

Film	Cat. No.
CX5-14 Film (with condenser system)	SH31137.01
CX5-14 Film (no condenser system)	SH31138.01
Aegis5-14 Film (with condenser system)	SH31136.01
Aegis5-14 Film (no condenser system)	SH31135.01

Table 9. 2,000 L standard 5:1 S.U.B. BPC specifications.

Description		Tubing set (inner diameter x outer diameter x length)	End treatment
1–5.	Probe ports (5)	12.7 mm (1/2 in.) tube ports	CPC AseptiQuik G genderless connectors
6.	Bottom drain harvest	19.1 mm (3/4 in.) x 25.4 mm (1 in.) C-Flex tubing x 122 cm (48 in.) splits to 12.7 mm (1/2 in.) x 19.1 mm (3/4 in.) C-Flex tubing x 61 cm (24 in.) reduced to 6.4 mm (1/4 in.) x 9.5 mm (3/8 in.) C-Flex tubing x 30 cm (12 in.) and 12.7 mm (1/2 in.) x 19.1 mm (3/4 in.) C-Flex tubing x 61 cm (24 in.)	1/4 in. MPC insert and Pall Kleenpak™ (male)
7.	Cross-flow sparger	6.4 mm (1/4 in.) x 11.1 mm (7/16 in.) C-Flex tubing x 8 cm (3 in.) connected to check valve and 6.4 mm (1/4 in.) x 11.1 mm (7/16 in.) C-Flex tubing x 183 cm (72 in.)	Meissner Steridyne™ 50 mm filter
8.	Thermowell/ small-volume sample	Thermowell adapter for 6.4 mm (1/4 in.) diameter 3.2 mm (1/8 in.) x 6.4 mm (1/4 in.) C-Flex tubing x 61 cm (24 in.)	SterilEnz™ pouch with injection site assembly
9.	Condenser bag assemblies (2)	Condenser bag assembly (optional)	–
10.	Condensate return line	Condenser bag assembly (optional)	–
11.	Exhaust lines (2)	Condenser bag assembly (optional)	–
12.	Overlay gas sparger	12.7 mm (1/2 in.) x 19.1 mm (3/4 in.) C-Flex tubing x 10 cm (4 in.) reduced to 9.5 mm (3/8 in.) x 15.9 mm (5/8 in.) C-Flex tubing x 213 cm (84 in.)	Kleenpak™ Emflon™ II capsule and pressure transducer
13.	Pressure sensor port	12.7 mm (1/2 in.) x 19.1 mm (3/4 in.) C-Flex tubing x 8 cm (3 in.)	CPC AseptiQuik aseptic connector
14–15.	Feed lines (2)	12.7 mm (1/2 in.) x 19.1 mm (3/4 in.) C-Flex tubing x 10 cm (4 in.) splits to 12.7 mm (1/2 in.) x 19.1 mm (3/4 in.) C-Flex tubing x 25 cm (10 in.) and 12.7 mm (1/2 in.) x 19.1 mm (3/4 in.) C-Flex tubing x 25 cm (10 in.)	SterilEnz pouch with injection site assembly and 9.5 mm (3/8 in.) MPC body
16.	Base addition	12.7 mm (1/2 in.) x 19.1 mm (3/4 in.) C-Flex tubing x 8 cm (3 in.) reduced to 6.4 mm (1/4 in.) x 11.1 mm (7/16 in.) C-Flex tubing x 213 cm (84 in.) reduced to 3.2 mm (1/8 in.) x 6.4 mm (1/4 in.) C-Flex tubing x 30 cm (12 in.)	Plugged
17.	Inoculum addition	12.7 mm (1/2 in.) x 19.1 mm (3/4 in.) C-Flex tubing x 8 cm (3 in.) reduced to 6.4 mm (1/4 in.) x 11.1 mm (7/16 in.) C-Flex tubing x 15 cm (6 in.) reduced to 3.2 mm (1/8 in.) x 6.4 mm (1/4 in.) C-Flex tubing x 213 cm (84 in.)	Plugged
18–19.	Drilled-hole sparger (2): 17.1 cm (6.75 in.) disk with 1,380 (690 x 0.582 mm) (0.023 in.) holes	9.5 mm (3/8 in.) x 15.9 mm (5/8 in.) C-Flex tubing x 8 cm (3 in.) connected to check valve and 9.5 mm (3/8 in.) x 15.9 mm (5/8 in.) C-Flex tubing x 183 cm (72 in.)	Meissner Steridyne 0.2 µm hydrophobic filter with 9.5 mm (3/8 in.) C-Flex tubing (Y-connector and quick connects provided for joining lines)
20–22.	Media fill/ auxiliary drain lines (3)	19.1 mm (3/4 in.) x 25.4 mm (1 in.) C-Flex tubing x 213 cm (84 in.) splits to 12.7 mm (1/2 in.) x 19.1 mm (3/4 in.) C-Flex tubing x 61 cm (24 in.) and 12.7 mm (1/2 in.) x 19.1 mm (3/4 in.) C-Flex tubing x 61 cm (24 in.)	CPC AseptiQuik G genderless connectors

Custom S.U.B. BPC options

Table 10 lists available custom 2,000 L S.U.B. BPC system options. Not all options are available for all ports.

Table 10. 2,000 L custom 5:1 S.U.B. BPC options.

Category	Options/capability	Notes
Tubing type	Thermoplastic elastomers: C-Flex™, Pharmed™, PharmaPure™ platinum-cured silicone PVC	More information is available in the component selection guide
Tubing size	Ranging from 0.318 to 2.54 cm (1/8 to 1 in.) ID, in customer-specified lengths	More information is available in the component selection guide
Connectors	Luers, quick connects, SIP connectors, Tri-clamp, aseptic connectors, sterile connectors, steam-to, steam-through, sample ports, plugs	More information is available in the component selection guide
Probe ports	Additional ports: second row of four	The reusable probe port connection uses a Kleenpak connector only
Disposable sensors	Pressure sensor: PendoTECH and Finesse Solutions DO and pH: Finesse Solutions and PreSens pH: Mettler Toledo	Choice of qualified sensors available
Additional probe ports	Limited engineer-to-order customization only	Qualified location on second row of probe ports only
Port sizes	Limited engineer-to-order customization only	Dependent on location in BPC and fit with hardware (e.g., 2.54 cm (1 in.) port on harvest line)
Rearrangement of lines on existing ports	Limited customization possible (e.g., moving sample/thermowell port to a probe tube port, or swapping overlay inlet line with supplement line)	Dependent on location in BPC and fit with hardware
Sparger	Dual sparger (drilled hole and cross-flow) standard	Sparger locations are fixed
Diptube lines	Limited customization possible	Length cannot interfere with impeller and shaft
Overlay and sparger line filters	Filter options available from standard component library	Choice of qualified filters available
Vent filters	Standard is Pall or Meissner 0.2 µm exhaust vent filter	Filters must be compatible with available vent filter heater configurations
Vent filter tubing length	Extended filter height above the S.U.B. BPC is made to order	Must be compatible with a vent filter bracket option
Filters on media and supplement inlets	Limited engineer-to-order customization only; choice of filters used to sterilize incoming media or supplements are available	Choice of qualified filters available

External controller options

The HyPerforma S.U.B. is offered with a DeltaV™ controller. This system was specifically designed and tested to be a complete out-of-the-box, ready-to-use solution for mammalian cell culture applications. Finesse Solutions, now a part of Thermo Fisher Scientific, offers additional strength in providing integrated products.

The user can also choose an open-architecture system, which allows you to integrate with any controller of your choice. Capital investment may also be reduced by utilizing a control system already in use in your facility. These systems work on DeltaV, Allen-Bradley, or Siemens software platforms. The HyPerforma S.U.B. can be integrated with many different controller systems. Please talk to your account representative about your specific controller integration needs.

Ordering information

Description	Quantity	Cat. No.
S.U.B. hardware unit	1	SUB2000.9009
S.U.B. BPC CX5-14 film with condenser system	3	SH31137.01
S.U.B. BPC Aegis5-14 film with condenser system	3	SH31136.01
Bioreactor probe assembly with CPC AseptiQuik connector (nonsterile for use in autoclave)	12	SH30720.02
Bioreactor probe assembly with Kleenpak connector (nonsterile for use in autoclave)	12	SH30720.01
Heavy-duty tubing clamp	12	SV20664.01
Autoclave tray for autoclaving probe accessories	1	SV50177.01
Auxiliary components supporting the Single-Use Bioreactor (supplied by end user or requested turnkey)		
Necessary for gas flow control, DO, and pH set points	1	Bioreactor control system
Autoclavable probe (13 mm x 13.5 PG thread with 195–235 mm insertion length)	*	DO probe
Autoclavable probe (13 mm x 13.5 PG thread with 195–235 mm insertion length)	*	pH probe
Tubing welder, steam-in-place system, sterilizer or laminar flow hood	*	Sterile/aseptic connection
Used for fluid transfer between linesets on the containers	*	Stand-alone peristaltic pump
Necessary for temperature controls (not provided)	*	Temperature control unit (TCU)

* Quantity based on needs.

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