

HyPerforma 5:1 50 L Single-Use Bioreactor with controller

Introduction

The integrated 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, integrated with a G3Lite™ controller, and a HyPerforma S.U.B. BioProcess Container (BPC), which is available in 50, 100, and 250 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.

This data sheet provides information on the integrated HyPerforma S.U.B. system, which includes the tank and standard S.U.B. BPC. The BPC utilizes dual-sparger design for cultures at nominal volume and a crossflow sparger strategically positioned just above the liquid volume for seed cultures. Both sparge designs have been rigorously tested and proven to offer high $k_L a$ values and optimal CO_2 stripping for improved pH control and decreased foaming.

The G3Lite bioreactor controller is a cart-mounted, self-contained unit that can be operated independently or networked. The controller is engineered to minimize capital expenditure without sacrificing functionality. G3Lite bioreactor controllers leverage the latest technologies such as SmartParts™, SmartSensors™, and TruBio™ software to enable easy, reliable, and repeatable process development and cell culture optimization.



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

- S.U.B. hardware unit available in integrated format
- Complete mixing system with water jacket
- Drive shaft inserts into the S.U.B. BPC through the mixing drive motor, and locks into the BPC agitator assembly
- Temperature control unit (TCU) and necessary tubing valve kit to connect to the vessel jacket inlet and outlet

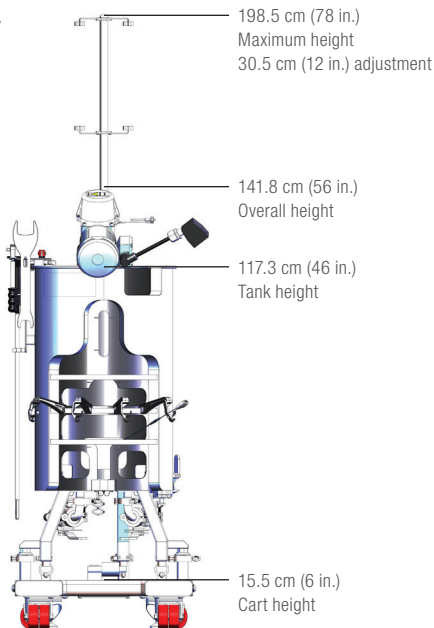
S.U.B. BPC (gamma irradiated and ready to use)

- Agitator assembly is a single-use impeller with a bearing-and-seal assembly linked to an external mixer drive
- Crossflow sparger for efficient culturing at low volumes (20%) and drilled-hole sparger with overlay sparge for 20–100% volumes
- Exhaust filter with heater for effective exhaust management of metabolic gases
- Integrally sealed ports in the S.U.B. BPC allow for additional sensor probes and line sets
- Available in Thermo Scientific™ CX5-14 and Aegis™ 5-14 film options

System options (adaptable to your needs)

- Additional exhaust gas vent filter heaters
- Cable management tree

Front view

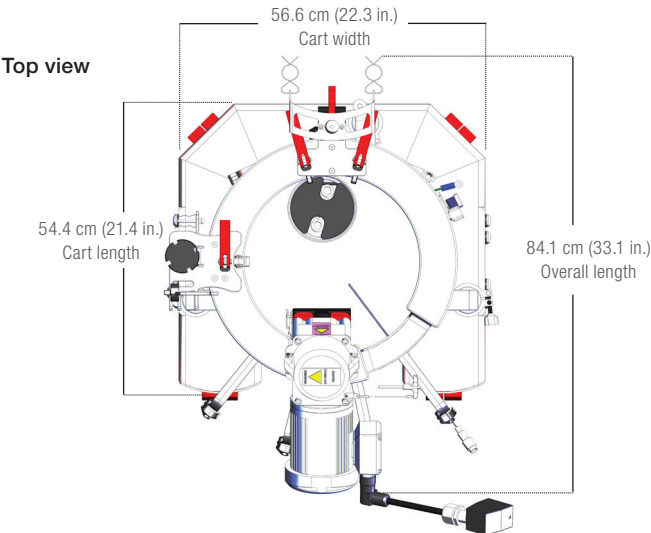


Standard HyPerforma 5:1 S.U.B. hardware units

The 50 L standard S.U.B. hardware units are available in configurations that include a water jacket with AC motor.

Table 1. 50 L standard 5:1 S.U.B. hardware unit with casters (leveling feet).

Description	Volume	Cat. No.
Water jacketed, 120/240 VAC, AC motor	50 L	SUB0050.8100.SDI



G3Lite controller



Figure 1. 50 L 5:1 S.U.B. and G3Lite controller hardware unit dimensions.

Design features

1. Exhaust vent filter holder (optional)
2. Mixing assembly with shield
3. Mixer motor
4. Bearing port receiver with clamp
5. Liquid sight windows
6. Probe hanger bracket
7. Probe access windows
8. Leveling casters
9. Load cells
10. Standard tool set: 3/8 in. x 150 in.-lb. square torque wrench, load cell, and motor cap lockout wrench
11. Drive shaft (stored)
12. Stainless steel (grade 304) outer support container
13. Bleed valve
14. 3/8 in. dimpled jacket (side)
15. Cart assembly
16. Bottom cutouts/pins for BPC attachment/alignment
17. Quick-connect water inlet/outlet ports

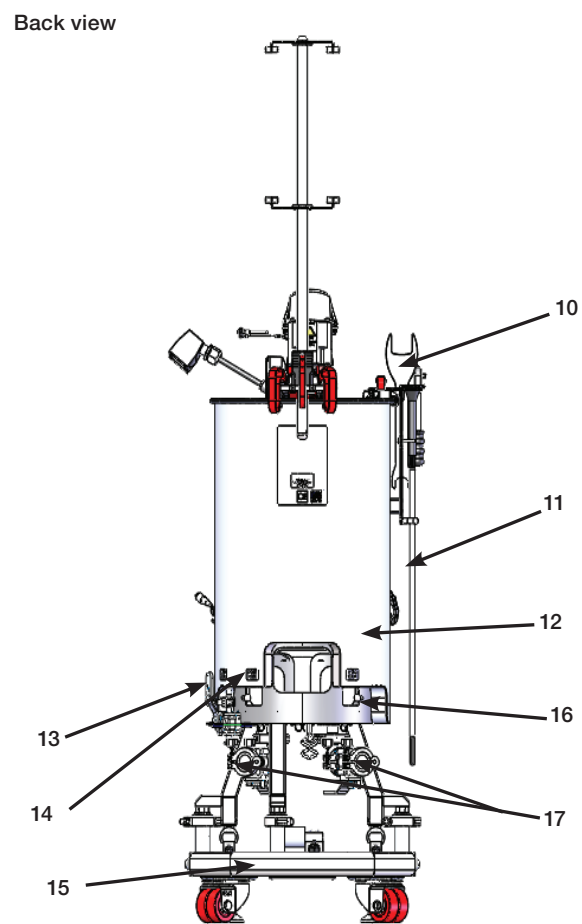
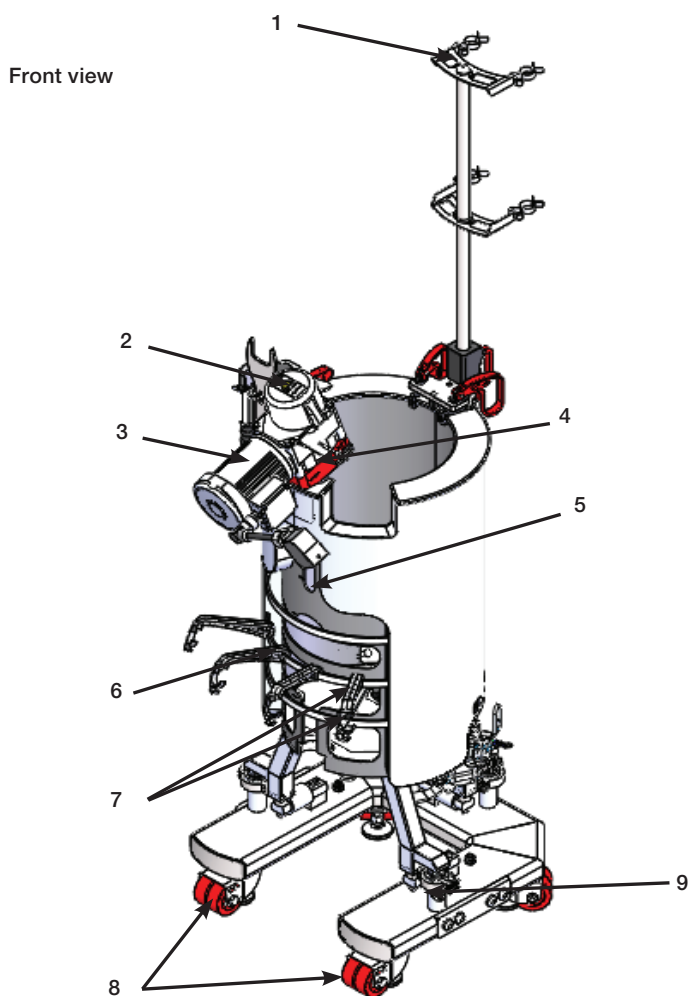


Figure 2. 50 L 5:1 S.U.B. hardware unit.

Table 2. 50 L Standard 5:1 S.U.B. system specifications.

		AC motor
Bioreactor geometry	Rated liquid working volume	50 L
	Minimum liquid working volume	10 L
	Total reactor volume (liquid and gas)	65.5 L
	BPC chamber diameter	34.9 cm (13.75 in.)
	BPC chamber shoulder height	80 cm (31.5 in.)
	Liquid height at rated working volume	52.1 cm (20.5 in.)
	Fluid geometry at working volume (height:diameter ratio)	1.5:1
	Overall reactor geometry (height:diameter ratio)	1.9:1
	Tank baffles	No
Impeller	Impeller (quantity x blade count)	1 x 3
	Impeller scaling (impeller diameter/tank diameter)	1/3
	Impeller blade pitch (angle)	45°
	Impeller diameter	11.11 cm (4.375 in.)
	Impeller, calculated power number (N)	2.1
Agitation	Maximum mixing rate	30–200 rpm
	Nominal agitation rating (power/volume)	20 W/m ³
	Nominal agitation, 20% working volume	107 rpm
	Nominal agitation, 50% working volume	145 rpm
	Nominal agitation, 100% working volume	183 rpm
	Nominal tip speed	103.9 cm/s (204.6 ft/min)
	Counterclockwise mixing flow direction	Down-pumping
	Agitation shaft resolved angle	16.5°
	Agitation shaft centerline offset	1.9 cm (0.75 in.)
	Overall drive shaft length	85.09 cm (33.5 in.)
	Drive shaft diameter	1.27 cm (0.5 in.)
	Drive shaft poly-sheath outside diameter	2.5 cm (1 in.)
	Impeller clearance from tank bottom	4.83 cm (1.9 in.)

Table 2. 50 L standard 5:1 S.U.B. system specifications (continued).

		AC motor
Motor	Agitation motor drive (type, voltage, phase)	Induction, 208 VAC, 3 phase
	Motor power rating	186.4 W (0.25 hp)
	Motor torque rating	9.5 N-m (82 in.-lb)
	Gear reduction	10:1
	Programmable variable-frequency drive (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	4.4/2 ft ²
	Jacket volume	2.4 L
	Jacket flow rate at 3.4 bar (50 psi)	136 L/min
	Process connection	1.5 in. sanitary tri-clamp
	Nominal heating/cooling load	500 W
	Approximate liquid heat-up time (5–37°C), 20% volume	1 hr
	Approximate liquid heat-up time (5–37°C), 100% volume	1.1 hr
	Resistance temperature detector (RTD) or thermocouple, 3.18 mm (1/8 in.) OD	RTD: Pt-100 (standard)
Support container	Overall width	56.6 cm (22.3 in.)
	Overall length	84.1 cm (33.1 in.)
	Overall height	141.8 cm (56 in.)
	Dry skid weight (mass)	115.7 kg (255 lb)
	Wet skid weight, rated working volume (mass)	165.7 kg (365.2 lb)
General	Ceiling height required for drive shaft loading	208.5 cm (82.1 in.)
	Electrical power supply requirement (voltage, phase, current)	120/240 VAC, single, 20/10 A
	pH and DO probe, autoclavable type (Applisens™, Finesse™, Mettler-Toledo™)	12 mm diameter x 215–235 mm insertion length x 13.5 PG (pipe) thread
	Noise level	< 70 dB at 1.5 m
Recommended operating parameters	Operating temperature range	Ambient to 40 ± 0.5°C (104 ± 0.9°F)
	Motor speed	30–200 rpm
	Volume range	10–50 L
	Maximum BioProcess Container pressure	0.03 bar (0.5 psi)
	Continuous operating time	21 days mixing time at nominal volume only

Table 3. G3Lite bioreactor controller specifications.

Description	Specifications
Utility tower dimensions (H x W x D)	1,600 x 680 x 540 mm (63 x 27 x 21 in.)
Enclosure rating	NEMA12/IP52
Operating temperature	5–40°C (41–104°F)
Storage temperature	–25–70°C (–15–158°F)
Relative humidity	5–95% noncondensing
Certifications	Manufactured to conform to CE specifications EN-60101 and EN-61325
Weight/shipping weight	68 kg/136.1 kg (150 lbs/300 lbs)
Agitation	HyPerforma S.U.B.s 1/4 hp or 1/2 hp AC 3-phase induction motor
pH (up to 2 inputs)	TruSens™ transmitter (electrochemical), TruFluor™ pH transmitter (single-use)
DO (up to 2 inputs)	TruSens transmitter (electrochemical), TruFluor DO transmitter (single-use)
Temperature	TruSens transmitter (RTD) and/or TruFluor pH and DO transmitters (single-use)
Pressure	TruTorr™ transmitter (single-use)
Liquid control	4 variable-speed peristaltic SmartPumps, Watson Marlow™ Series 114 or 313
	S.U.B. pumps
	Pumps
	Antifoam, base, feed Watson Marlow 114
	Media Watson Marlow 313
Gas control (TruFlow)	6 MFCs with 3 output connectors
	MPC flow range, LPM
	Air
	O₂
	N₂
	CO₂
	DHS sparge 5 5 2 1
	Crossflow/overlay 5 - - -
	Spare 2 - - -
Scales/load cells	SmartScale transmitter
Auxiliary	2 analog inputs (12-bit, 4–20 mA); 2 auxiliary control loops (4–20 mA)
Digital output	2 outputs (24 V); 1 dry relay alarm contact
Thermal control	Analog temperature control unit (TCU)
Vent filter heaters	50 L, 100 L: 2 heaters for Pall KA3™ filters 250 L: 2 Meissner UltraCap™ 10 in. filters
External pumps	Up to 2 additional external SmartPumps, Watson Marlow™ Series 114, 313, 520, 620; Freestanding or on a SmartPump tower
pH cables	K8, VP, TruFluor
DO cables	D4, VP6, VP8, TruFluor
Vent filter heater connection	IEC 60309 6H receptacle 2P+E or external heater power box for larger jacketed SUBs
SUBs (single-use vessels)	50, 100, 250 L
HMI	NEMA 4X, 22 in. touch-screen monitor, with KVM, with keyboard and pointing devices

System options

Table 4 lists available S.U.B. system options for the 50 L size.

- **Bioreactor probe assembly** (Figure 3)—required for each sterile electrochemical probe insertion; new CPC AsepticQuik™ connector is used on probe assembly SH30720.02 and mating probe belt on S.U.B. BPC for connection
- **Sparge line support** (Figure 4)—keeps gas lines in an upright position for optimal gas transfer
- **Heavy-duty tubing clamp** (Figure 5)—used for each probe port not in use, eliminating process fluid holdup
- **Autoclave tray for probe kits** (Figure 6)—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 prevent probe bellows from collapsing during sterilization

Table 4. 50 L S.U.B. system options.

Description	Cat. No.
Cable management tree	SV50992.01
Load cell with summation box, without display	SV50988.01
Autoclave tray	SV50177.01
Bioreactor probe assembly with CPC AsepticQuik connector (nonsterile for use in autoclave)	SH30720.02
Sparge line support	SV50177B.19
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
Finesse pressure sensor assembly	SH31134.02



Figure 3. Bioreactor probe assembly.



Figure 4. Sparge line support.



Figure 5. Heavy-duty tubing clamp.

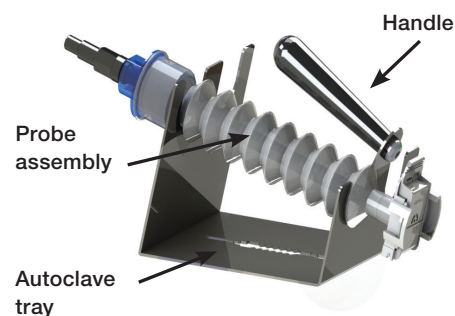


Figure 6. Autoclave tray for probe kits.



Figure 7. Temperature sample port.



Figure 8. Load cells.



Figure 9. Cable management tree.

- **S.U.B. temperature sample port** (Figure 7)—provides *insitu* temperature monitoring during culture process
- **Load cells** (Figure 8)—Mettler-Toledo™ FlexMount™ load cells allow for batch liquid-weight reading and three load cells; three load cells are mounted with summing box on the S.U.B. hardware unit
- **Cable management tree** (Figure 9)—allows the end user to organize the S.U.B. BPC tubing lines for operator ease of use
- **Sterile sampling manifolds**—available in 50 and 100 mL sizes for off-line sample retention

Vent heaters

Vent heaters aid in reducing moisture buildup in exhaust filters from system off-gassing. Vent heaters are factory-preset at 50°C, to allow condensation to return to the vessel. Recommended gassing strategies of the S.U.B. system are in the S.U.B. Validation Guide. Table 5 lists available vent heaters.

Table 5. Vent heater required for each exhaust filter on S.U.B. BPC.

Description	Cat. No.
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, M12–5 pin connector*	SV50191.45
240 VAC, 30.3 W, Pall Kleenpak KA3 series 46-vent filter heater, integrated, M12–5 pin connector*	SV50191.46

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

Spare parts

Table 6 lists the available spare parts of the 50 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 6. Available spare parts.

Description	Cat. No.
AC motor	SV50237.16
Drive shaft	SV50959.10
RTD 304.8 cm (120 in.) with Bulgin connector	SV50177.363
Probe holders	SV50177.23
Probe kit autoclave (SST with plastic carry handle)	SV50177.01
Adjustable filter bracket	SV50177.313

Table 8. 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 (25–40 kGy) inside outer packaging
Shipping container	Durable cardboard carton
Documentation	Certificate of Analysis provided with each lot for delivery

Standard 5:1 S.U.B. BPC systems

Table 7 shows the available standard 50 L S.U.B. BPC system options with drilled-hole, crossflow, and overlay spargers. Standard S.U.B. BPC packaging is shown in Table 8.

Table 7. 50 L Standard 5:1 S.U.B. BPCs.

Size	Film	Cat. No.
50 L	CX5-14	SH31072.01
50 L	Aegis5-14	SH31073.01

* See standard drawing specifications below.

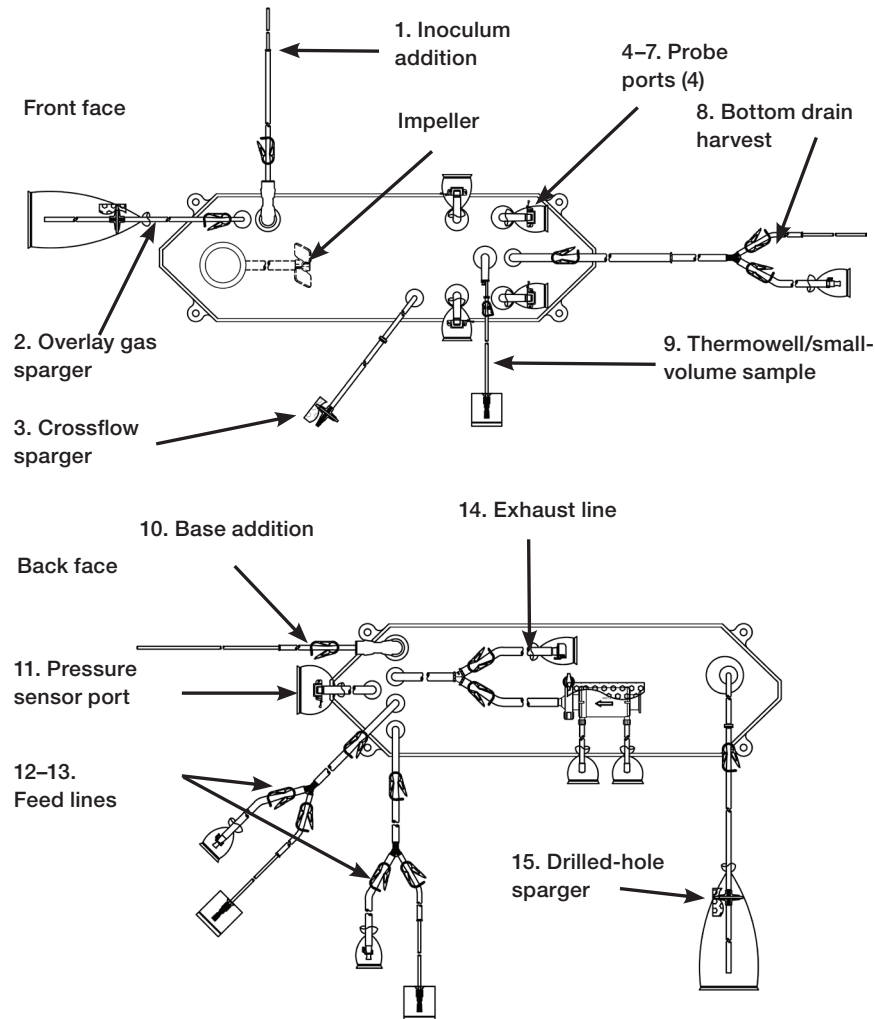


Figure 10. 50 L Standard 5:1 S.U.B. BPC.

Table 9. 50 L standard 5:1 S.U.B. BPC specifications

Description		Tubing set (inner diameter x outer diameter x length)	End treatment
1.	Inoculum addition	6.4 mm (1/4 in.) x 11.1 mm (7/16 in.) C-Flex™ tubing x 152 cm (60 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
2.	Overlay gas sparger	6.4 mm (1/4 in.) x 11.1 mm (7/16 in.) C-Flex tubing x 15 cm (6 in.)	Hydrophobic vent filter with Emflon™ II, connected to 15 cm (6 in.) C-Flex tubing
3.	Crossflow 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
4–7.	Probe ports (4)	12.7 mm (1/2 in.) tube ports	CPC AseptiQuik aseptic connectors
8.	Bottom drain harvest	12.7 mm (1/2 in.) x 19.1 mm (3/4 in.) C-Flex tubing x 152 cm (60 in.) reduced to 9.5 mm (3/8 in.) x 15.9 mm (5/8 in.) C-Flex tubing x 30 cm (12 in.) splits to 6.4 mm (1/4 in.) x 11.1 mm (7/16 in.) C-Flex tubing x 30 cm (12 in.) reduced to 3.2 mm (1/8 in.) x 6.4 mm (1/4 in.) C-Flex tubing x 30 cm (12 in.) and 9.5 mm (3/8 in.) x 15.9 mm (5/8 in.) C-Flex tubing x 30 cm (12 in.)	Plugged and 9.5 mm (3/8 in.) MPC insert
9.	Thermowell/small volume sample	Thermowell adapter for 3.2 mm (1/8 in.) diameter RTD and 3.2 mm (1/8 in.) x 6.4 mm (1/4 in.) C-Flex tubing x 46 cm (18 in.)	Luer lock and SterilEnz™ pouch with injection site assembly
10.	Base addition	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 152 cm (60 in.)	Plugged
11.	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
12–13.	Feed lines	9.5 mm (3/8 in.) x 15.9 mm (5/8 in.) C-Flex tubing x 152 cm (60 in.) splits to 6.4 mm (1/4 in.) x 11.1 mm (7/16 in.) C-Flex tubing x 30 cm (12 in.) reduced to 3.2 mm (1/8 in.) x 6.4 mm (1/4 in.) C-Flex tubing x 30 cm (12 in.) and 9.5 mm (3/8 in.) x 15.9 mm (5/8 in.) C-Flex tubing x 30 cm (12 in.)	SterilEnz pouch with injection site assembly and 9.5 mm (3/8 in.) MPC body
14.	Exhaust line	12.7 mm (1/2 in.) x 19.1 mm (3/4 in.) C-Flex tubing x 20 cm (8 in.) connected to 12.7 mm (1/2 in.) x 19.1 mm (3/4 in.) C-Flex tubing x 15 cm (6 in.) and 12.7 mm (1/2 in.) x 19.1 mm (3/4 in.) C-Flex tubing x 25 cm (10 in.)	CPC AseptiQuik aseptic connector—Kleenpak 0.2 µm exhaust vent filter
15.	Drilled-hole sparger 8.9 cm (3.5 in.) disk with 360 x 0.178 mm (0.007 in.) holes	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 97 cm (38 in.)	Meissner Steridyne 0.2 µm hydrophobic filter connected to 15 cm (6 in.) C-Flex

Custom S.U.B. BPC options

Table 10 lists available custom 50 L S.U.B. BPC system options. Not all options are available for all ports. For additional information, please see the selection guides in the S.U.B. BPC catalog.

Table 10. Custom 50 L S.U.B. BPC options.

Category	Options/capability	Notes
Tubing type	Thermoplastic elastomers: C-Flex™, PharMed™, PharmaPure™, tubing; Platinum-cured silicone PVC	More information is available in the component selection guide
Tubing size	Ranging from 0.318 to 2.54 cm (1/8–1 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: Finesse Solutions DO and pH: Finesse Solutions	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	Drilled-hole, crossflow, and overlay spargers 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 is available	Choice of qualified filters available

Ordering information

Product	Quantity	Cat. No.
S.U.B. hardware unit: 50 L	1	SUB0050.8100.SDI
S.U.B. BPC: 50 L	3	SH31072.01 (CX5-14 film) SH31073.01 (Aegis5-14 film)
Bioreactor probe assembly with CPC AseptiQuik (nonsterile for use in autoclave)	12	SH30720.02
Heavy-duty tubing clamp	12	SV20664.01
Autoclave tray for autoclaving probe accessories	1	SV50177.01
Auxiliary components supporting the HyPerforma S.U.B. (supplied by end user or requested turnkey)		
Necessary for feed strategies, gas flow, DO, and pH control	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, 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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