CHAPTER 1

Cardiopulmonary bypass equipment

Cardiopulmonary bypass (CPB) equipment is a specialty in and of itself. Perfusionists are very often the only in-house clinicians who fully understand the capabilities and limitations of the disposables and hardware they are charged with setting up, operating, maintaining, and troubleshooting. Therefore, for optimal patient safety, perfusionists must first and foremost be experts with this equipment. That cannot be overstated. Reading instructions for use (IFU) manuals is essential for starting to understand a device's capabilities and limitations. Team discussion, simulation training, and hands-on experience then round out one's understanding of a product before clinical use.

The CPB plan starts with basics of patient height, weight, body surface area (BSA), allergy history, original diagnosis, previous surgeries, current indications for surgery, and the surgical plan. The perfusionist must select and assemble an array of equipment matched to the patient's size, expected pump flow rates, factors related to the diagnosis, and the planned intervention. The following is an overview of the major components of a heart–lung machine (HLM) set up. Please refer to Chapter 6, *Cardiac Lesions and Operations with Cardiopulmonary Bypass* for case-specific guidance. Figure 1.1 is provided as a reference schematic for the basic CPB circuit arrangement and connections to the patient at the sterile field.

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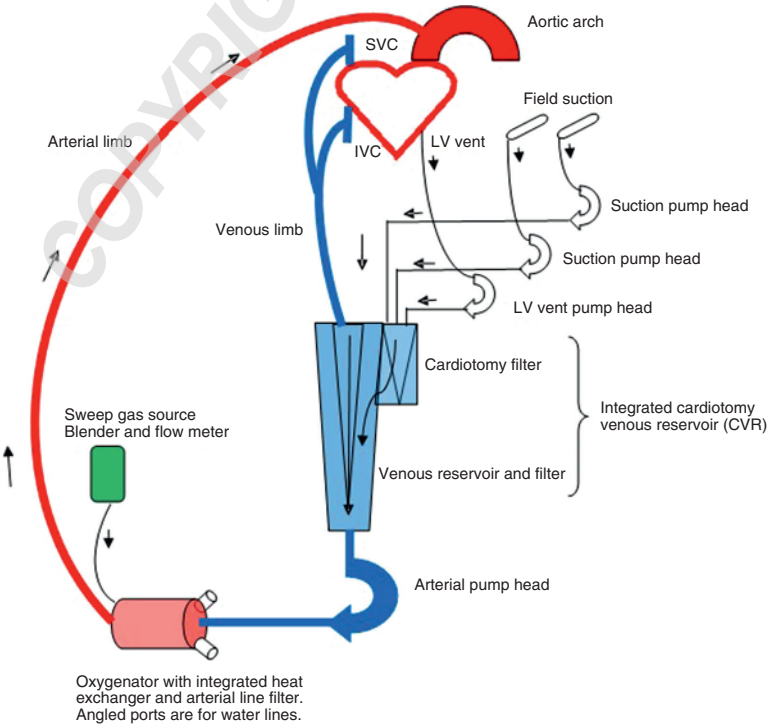


Figure 1.1 Simplified schematic for basic CPB equipment (excludes cardioplegia system).

Oxygenators

The device commonly referred to as the "oxygenator" is actually several integrated items, which, in addition to the oxygenating membrane may include the arterial line filter (ALF), venous reservoir and filter, cardiotomy filter, and heat exchanger. The "oxygenator" commonly refers to the oxygenator-reservoir system. Figure 1.2 labels the primary components, the cardiotomy venous reservoir (CVR) and oxygenator membrane, of the Terumo (Ann Arbor, MI) CAPIOX FX series of "oxygenators." Figure 1.3 depicts typical components of an oxygenator-reservoir system.

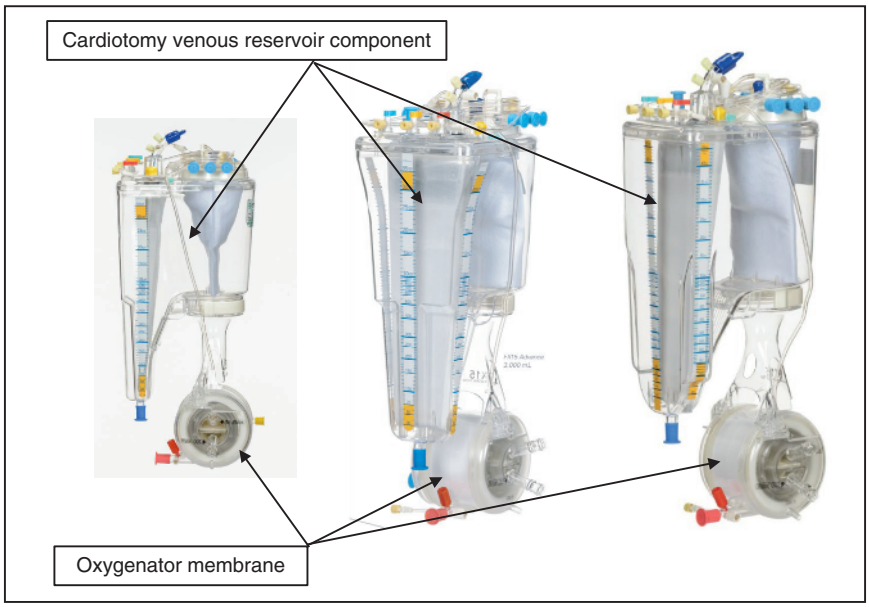


Figure 1.2 Terumo CAPIOX FX series of oxygenators. *Left to right: FX05, FX15-30 Advance, FX25 Advance*. Reproduced with permission from Terumo Cardiovascular Group, Ann Arbor, MI. All rights reserved.

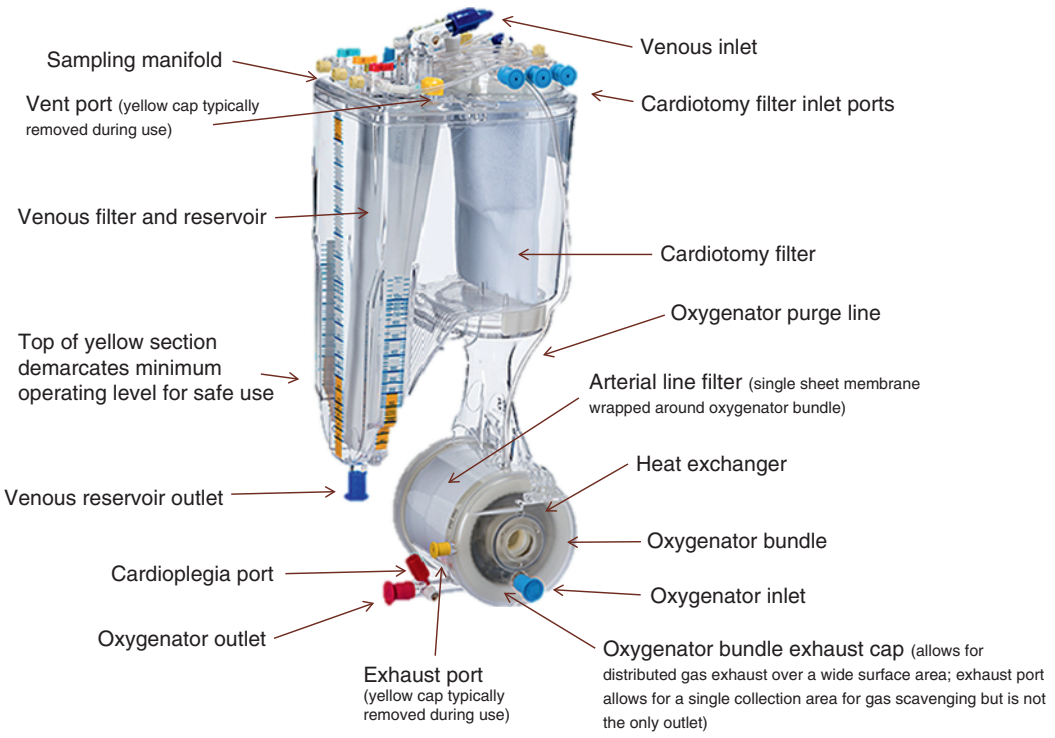


Figure 1.3 Typical components of an oxygenator-reservoir system. Terumo CAPIOX Advance FX25 image reproduced with permission from Terumo Cardiovascular Group, Ann Arbor, MI. All rights reserved.

The oxygenator membrane

- The oxygenator "membrane" may also be referred to as the oxygenator bundle.
- Membrane oxygenators allow for diffusion of gas, oxygen and carbon dioxide most importantly, across a material separating the blood path from the gas flow path (also called the blood and gas phases).
- Oxygenators for CPB are typically microporous hollow fiber membranes.
- Blood flow in oxygenators is always on the outside of the fibers and this is qualified as extraluminal blood flow. Conversely, blood flow through hemoconcentrators is normally within the fibers and this is termed intraluminal blood flow.
- Most hollow fiber membrane oxygenators (HFMO) are made of extruded microporous polypropylene fibers that are hydrophobic.
- True membrane oxygenators allow for diffusion of gases through a membrane separating the blood and gas phases (see Figure 1.4). The type and thickness of the membrane, as well as blood and gas flow characteristics on opposing sides, determine overall diffusion rates.
- Microporous hollow fiber membrane oxygenator bundle fibers are typically 200–300 μ in diameter. The wall thickness of these fibers ranges between 25 and 50 μ with a pore size of approximately 0.02 μ (1, 2).
- Microporous membrane oxygenators allow for diffusion of gases through microscopic holes in the membrane material (see Figure 1.4). The gas transfers directly through these micropores and is therefore less impacted by the membrane material. However, blood and gas flow characteristics on opposing sides still impact diffusion capacity.
- Blood proteins coat a membrane oxygenator's surface area, including the micropores through which gas exchange occurs.

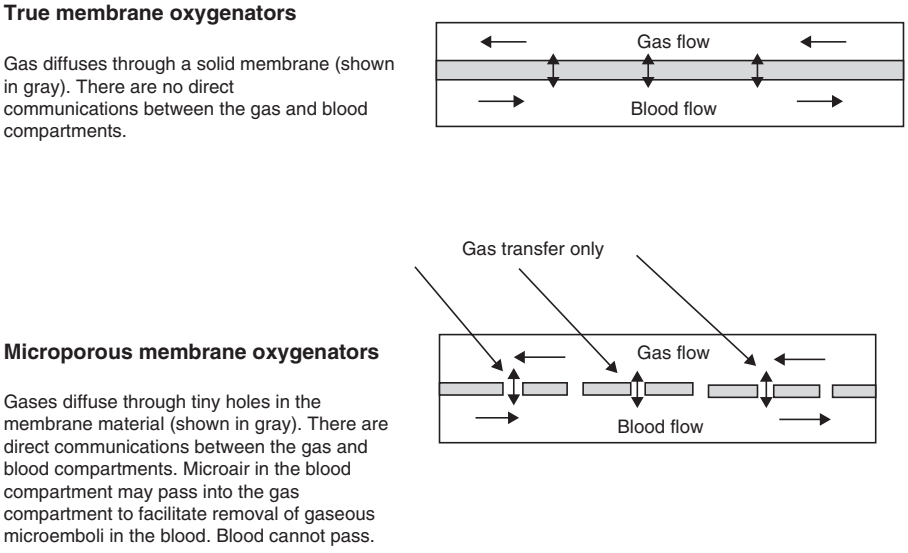


Figure 1.4 Primary types of oxygenator membranes.

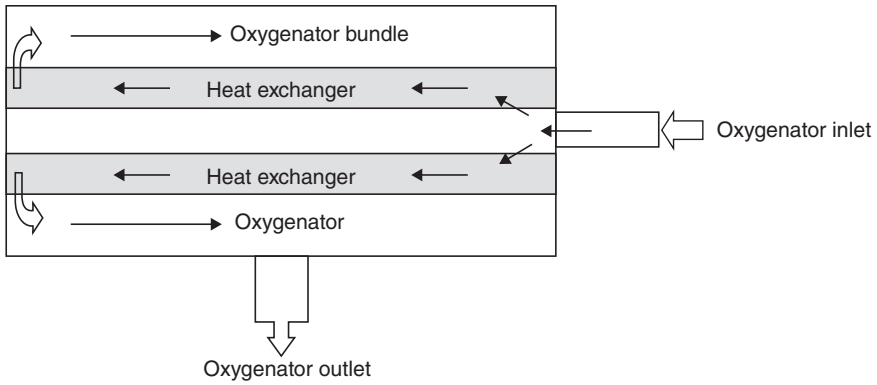
- Microporous membranes may experience increased protein coating with a subsequent decrease in oxygen transfer during extended bypass runs. It is important to note that this protein coating may also decrease the air handling capabilities of the membrane.
- All oxygenators on the market today for CPB are microporous membrane oxygenators. The membrane oxygenator must always be positioned below the reservoir to prevent the possibility of air entrainment through the hollow fibers, particularly at low-flow or no-flow time points, which could occur in certain situations if the HFMO is above the reservoir.
- Oxygenator-reservoir systems are commonly listed by the manufacturer as being rated for use up to 6 hours. This is the useful lifespan listed because it is the testing time limit required for FDA clearance (3). In clinical practice, oxygenators and reservoirs are only ever changed out when clinically indicated. This practice helps limit patient blood exposure to additional foreign surface area, which could impact

the systemic inflammatory response to extracorporeal support.

- The membrane oxygenator size chosen for a particular patient should be the smallest which will allow for safe perfusion with some degree of functional reserve in case of decreasing efficiency during extended bypass runs or to account for markedly increased pump flows due to major aortopulmonary collaterals (MAPCAs), surgical or other central shunts, or significant aortic regurgitation. Increased pump flow rates in these situations may be required to maintain adequate effective systemic perfusion.
- Perfusionists must be familiar with the manufacturer-defined limits for the gas flow to blood flow ($\dot{V}/\dot{Q}$) ratio since some devices specify not to exceed a certain value. All instructions for use (IFU) state that the blood phase pressure must always exceed the gas phase pressure, but clinical examples of when such a concern would present are generally lacking from manufacturers (4).
- The oxygenator sweep gas inlet commonly has a green cap for easy identification. This green cap is removed when attaching the sweep gas line.
- The oxygenator sweep gas outlet commonly has a yellow cap that is removed during circuit assembly or priming.
- The oxygenator sweep gas outlet(s) must never become blocked as this could cause air to enter the blood phase. Most oxygenators now come standard with a distributed sweep gas outlet arrangement (Figure 1.3). Here, the oxygenator bundle exhausts gas over a wide area that is covered by ventilated plastic housing. There may still be a singular sweep gas exhaust port, but this connection is provided only to allow for scavenging of exhaust gas. A scavenging line placed here captures the sweep gas exhaust and pulls in room air from the ventilated housing.
- It is well established that higher blood flow rates through a device can increase gaseous microemboli (GME) transmission. Using an oxygenator above its manufacturer-recommended maximum flow rate may increase arterial line GME transmission and is therefore not recommended (5–9).
- It is recommended to define the patient's BSA and select an oxygenator based on the maximum expected pump flow. It is important to note that for neonates and infants in particular, their relatively higher metabolic requirement may require markedly increased pump flows during normothermic bypass (i.e., rewarming). Index flows of 3.0–3.5 L/min/m^2 are not uncommon and should be considered for equipment selection. See *Chapter 6, Cardiac Lesions and Operations with Cardiopulmonary Bypass* for case-specific guidance where much higher flows must be accounted for with certain diagnoses.
- Primary consideration is given to the manufacturer-recommended maximum flow rate that is based on gas exchange and other aspects of oxygenator, heat exchanger, and reservoir performance. The American Association of Medical Instrumentation (AAMI) standard reference values are usually not relied solely upon since they may not take into account additional factors that the manufacturer evaluates for overall performance and patient safety.
- Increased oxygenator bundle size does not linearly relate to performance since characteristics of the blood and gas flow paths vary among devices.
- Microporous oxygenator bundles are important in the removal of air from the blood phase and into the gas phase. GME removal in the oxygenator bundle is so well recognized that investigators have worked to maximize the phenomenon. While not clinically available, the use of hypobaric sweep gas pressures has been shown in an animal model to greatly reduce arterial circuit GME counts (10).
- Oxygenators have either radial or axial blood flow paths that affect performance in competing ways in regard to pressure drop and microemboli removal. Figure 1.5 provides a simplified schematic for these oxygenator blood flow paths. Axial flow paths provide a longer transit time and may allow for improved removal of GME but with higher transmembrane pressures. Radial flow paths allow for lower transmembrane pressures but also less transit time, which may impact oxygenator-level removal of GME.

Axial blood flow path

Blood travels along the axis of the heat exchanger first and then along the axis of the oxygenator bundle before exiting a low point in the device.



Radial blood flow path

Blood enters and radiates through the heat exchanger and oxygenator bundle before exiting a low point in the device. Some oxygenators preferentially have blood exit the heat exchanger top before flowing through the oxygenator bundle.

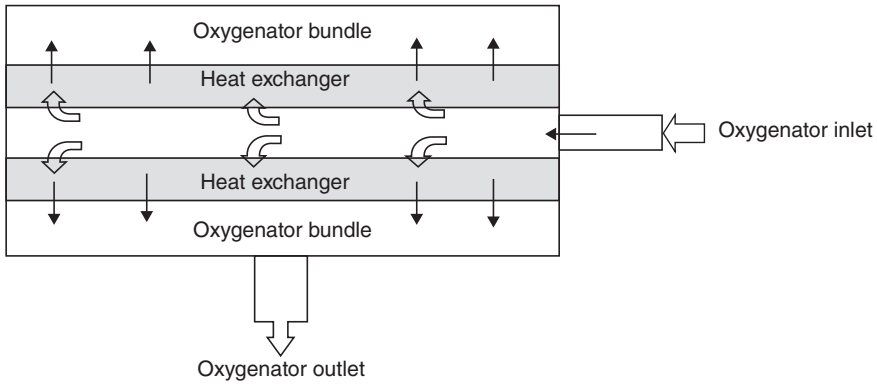


Figure 1.5 Simplified schematic of axial and radial blood flow paths through an oxygenator.

- The radial flow Medtronic Affinity Fusion (Minneapolis, MN) has taken advantage of the air handling capabilities of microporous oxygenators, and unique bundle wrapping technology, to be FDA approved for use as a 25 µ arterial depth filter as well as an oxygenator.
- The radial flow Terumo CAPIOX FX series of oxygenators includes a single sheet membrane with 32 µ pores wrapped around the oxygenator bundle to serve as an ALF.
- Spectrum Medical has introduced innovative dual-chamber oxygenator technology that creates an intentional $\dot{V}/\dot{Q}$ mismatch within the oxygenator by limiting the gas flow to a variable percentage of bundle fibers (11, 12). The dual oxygenator bundle receives only 100% oxygen to prevent the introduction of nitrogen into the system and to maximize off-gassing of nitrogen in the oxygenator as well as in the body into the blood. This system allows for PaO_2 control and GME control. *See Blood Gas Management in Chapter 3, The Cardiopulmonary Bypass Plan.*
- The perfusionist must be familiar with the *manufacturer's* recommendations for treating an oxygenator suspected of "wetting out" (4). Available values are listed in Tables 1.1 and 1.2.
- Manufacturers commonly qualify that oxygenator use beyond 6 hours may be associated with plasma leak into the gas phase of the device and decreased oxygenator performance (i.e., decreased gas exchange efficiency with decreased gas exchange surface area).
- Oxygenator use beyond 6 hours does occur and most often there is not a significant decrease in performance. However, safe use beyond this limit is not guaranteed. Consideration should be given to changing out an oxygenator after a long case in which an additional bypass run is a serious possibility. Elective change-out while off bypass can be accomplished in a controlled manner and can eliminate several concerns of emergently resuming bypass with a product at the end of its rated performance limit. Refer to *Chapter 8, Emergencies during Cardiopulmonary Bypass* for options to address oxygenator failure.
- The pressure drop across an oxygenator membrane is frequently listed as a specification. It may be measured in real time during bypass. A change in this value over time is important to consider during bypass as it can be an indicator of change in function.
- Pressure drop is frequently equated with shear stress where a lower pressure drop is considered beneficial

Table 1.1 CPB oxygenators rated up to 3.5 LPM.

Manufacturer	Oxygenator (microporous polypropylene except as noted)	Oxygenator bundle (m^2)	Oxygenator prime volume	Manufacturer recommended maximum blood flow rate (LPM)	Heat exchanger material/size (m^2)	Reservoir capacity (mL)	Surface- modifying agent type	Integrated arterial filter/ pore size	Minimum operating volume* (mL)	Gas flow range	Maximum temporary gas flow for suspected wetting out of oxygenator
LivaNova	D100	0.22	31	0.7	Stainless steel/0.03	500	Phosphorylcholine (PHISIO)	No/Typically paired with D130 external filter rated to 40 µ	10	Up to max $\dot{V}/\dot{Q}$ of 2:1	Up to max $\dot{V}/\dot{Q}$ of 4:1 for 10 minutes only
Terumo	CAPIOX FX05	0.50	43	1.5	Stainless steel/0.035	1,000	Terumo Xcoating™	Yes/32 µ with a surface area of 130 cm^2	15	Up to 5 LPM to briefly sigh membrane only	5 LPM for 10 s, do not repeat
LivaNova	D101	0.61	87	2.5	Stainless steel/0.06	1,500	Phosphorylcholine (PHISIO)	No/Typically paired with D131 external filter rated to 40 µ	30	Up to max $\dot{V}/\dot{Q}$ of 2:1	Up to max $\dot{V}/\dot{Q}$ of 4:1 for 10 minutes only
Eurosets *pending release in the USA*	Trilly Infant-Pediatric	0.84	99	3.0	Stainless steel/0.04	2,500 (recommended max 2,200)	Phosphorylcholine	Yes/38 µ as part of oxygenator bundle wrapping	100@3.5LPM, 50@2LPM, 30@0.5LPM	Info not available	None specified
Spectrum Medical *pending release*	VT-75: *polymethylpentene	0.8	75 +/–5	2.4	Not integral to device. Separate heat exchanger required	Reservoir not integral to device	Phosphorylcholine	Not specified	Reservoir not integral to device	Not specified	None specified
Eurosets *pending release in the USA*	Trilly Pediatric AF	1.1	130	3.5	Stainless steel/0.04	2,500 (recommended max 2,200)	Phosphorylcholine	Yes/38 µ as part of oxygenator bundle wrapping	100@3.5LPM, 50@2LPM, 30@0.5LPM	Up to 7 LPM	None specified

*Minimum operating levels are qualified at maximum recommended flow rates unless otherwise indicated.

Table 1.2 CPB oxygenators rated 5–8 LPM.

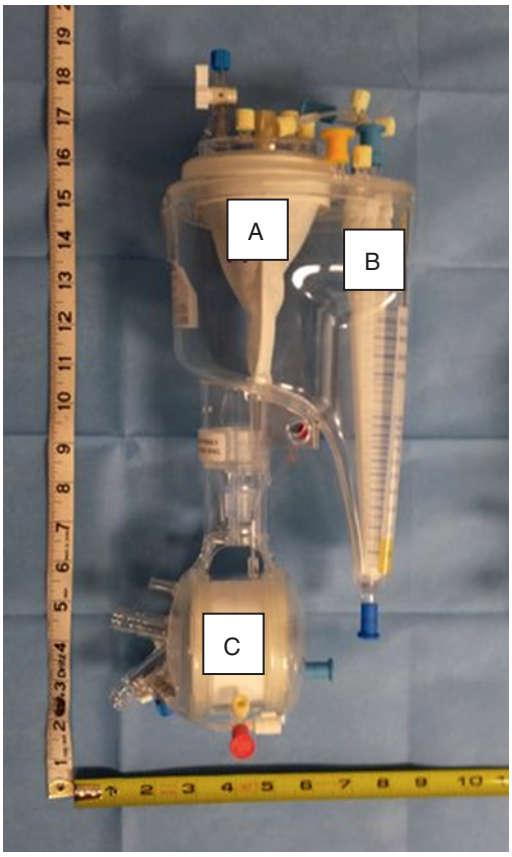
Manufacturer	Oxygenator (microporous polypropylene except as noted)	Oxygenator bundle (m^2)	Oxygenator prime volume	Manufacturer recommended maximum blood flow rate (LPM)	Heat exchanger material/size (m^2)	Reservoir capacity (mL)	Surface- modifying agent type	Integrated arterial filter/ pore size	Minimum operating volume	Gas flow range	Maximum temporary gas flow for suspected wetting out of oxygenator
Terumo	CAPIOX FX15 Advance	1.5	144	5.0	Stainless steel/0.14	3,000 or 4,000	Terumo Xcoating™	Yes/32 µ with a surface area of 360 cm^2	70 (3L reservoir) 150 (4L reservoir)	Up to 15 to briefly sigh membrane only	15 LPM for 10 s, do not repeat
LivaNova	Inspire 6 (optional integrated arterial filter)	1.4	184/ 284 with ALF	6.0	Polyurethane 0.4	4,500 *Optional hardshell dual and soft-shell reservoirs	Phosphorylcholine (PHISIO)	Optional/38 µ	150	Up to 12 LPM, not to exceed 2:1 $\dot{V}/\dot{Q}$	Up to 12 LPM, not to exceed 2:1 $\dot{V}/\dot{Q}$
Spectrum Medical *pending release	VT-160: *polymethylpentene	1.45	145 +/–10	5	Not integral to device. Separate heat exchanger required	Reservoir not integral to device	Phosphorylcholine	Not specified	Reservoir not integral to device	Not specified	None specified
Medtronic	Affinity NT	2.5	270	7.0	Stainless steel/Not specified	4,000	Balance™ (not heparin-based)	No	200	None specified	None specified
Medtronic	Affinity Fusion™	2.5	260	7.0	Polyethylene terephthalate/Not specified	4,500	Balance™ (not heparin-based) or Cortiva™ (heparin-based)	Yes/25 µ as part of oxygenator bundle wrapping	200	None specified	None specified
Terumo	CAPIOX FX25 Advance	2.5	260	7.0	Stainless steel/0.2	4,000	Terumo Xcoating™	Yes/32 µ sheet membrane with a surface area of 600 cm^2	150	Up to 20 LPM to briefly sigh membrane only	20 LPM for 10 s, do not repeat
LivaNova	Inspire 8 (optional integrated arterial filter)	1.75	219/ 351 with ALF	8.0	Polyurethane 0.4	4,500/41 µ *Optional hardshell dual and soft shell reservoirs	Phosphorylcholine (PHISIO)	Optional/38 µm	150	Up to 12 LPM, not to exceed 2:1 $\dot{V}/\dot{Q}$	Up to 12 LPM, not to exceed 2:1 $\dot{V}/\dot{Q}$
Terumo	CAPIOX NX19 *limited availability in the USA	1.9	185 (+/–10%)	8.0	Polyethylene Terephthalate/0.43 0.43	4,000	Terumo Xcoating™	Yes/32 µ sheet membrane with a surface area of 600 cm^2	150	Up to 20 LPM to briefly sigh membrane only; Do not exceed 2:1 $\dot{V}/\dot{Q}$ ratio	20 LPM for 10 s, do not repeat
Spectrum Medical *pending release	VT-200: *polymethylpentene	1.75	185 +/–10	7	Not integral to device. Separate heat exchanger required	Reservoir not integral to device	Phosphorylcholine	Not specified	Reservoir not integral to device	Not specified	None specified

with lower shear stress. That is not always the case since shear is not only related to pressure. Additionally, pressure drop plays an important role in microembolic air removal in microporous systems (13).

- It is commonly recommended to have water flowing through the heat exchanger when priming the oxygenator if PVC tubing is used in the pump boot. This is an important consideration since PVC tubing in a roller head can build up static electricity that is preferably dissipated through the water flow as opposed to the oxygenator bundle or any electronic circuitry. Static electricity discharge through an oxygenator membrane or a heart–lung machine component can lead to failure (14, 15).
- Volatile anesthetics, including sevoflurane and isoflurane, should not come in direct contact with the plastic components of the oxygenator device. Volatile anesthetic contact can cause leaching of plasticizer, weakening the structure leading to failure (16).

The venous reservoir

- Most pediatric centers use open hard-shell reservoirs. The term "open" refers to the reservoir being open to atmosphere for use in a system using gravity siphon drainage. The reservoir must be properly vented to prevent pressurization and the risk of air embolization to the patient. Pressure in the reservoir can result from sucker, vent, and venous inflow if air is not allowed to escape through a vent port or vacuum system. (*See Massive Air Embolism in Chapter 8, Emergencies during Cardiopulmonary Bypass and Standard and Augmented Venous Return in Chapter 3, The Cardiopulmonary Bypass Plan.*)
- CVRs typically contain an overpressure relief valve that may also incorporate a valve to limit overall negative pressure in the reservoir. These valves that include a duck bill design commonly have an insert placed through the valve during manufacturing to ensure the valve does not seal during the sterilization process. This insert must be removed during circuit set up or priming.
- "Closed" bypass systems commonly incorporate a bag design for the venous reservoir, which significantly limits the blood: air interface. Closed systems have been shown to have a decreased inflammatory response with fewer hematologic disruptions. However, closed systems have less precise visual monitoring of venous return, require additional systems for purging venous bag air, and are not readily converted to vacuum-assisted venous drainage.
- The venous reservoir contains the venous filter (see Figure 1.6).



A-cardiotomy filter in the CVR.
B-venous filter in the CVR.
C-arterial line filter wrapped around oxygenator bundle

Figure 1.6 Filters in the Terumo CAPIOX FX05 oxygenator-reservoir system.

- The venous reservoir generally collects venous blood and cardiotomy blood. Both venous blood and cardiotomy blood get filtered separately via different flow paths in the reservoir. The reservoir may therefore be referred to as the cardiotomy venous reservoir (see Figure 1.1).
- The reservoir capacity needs to handle the patient's blood volume in cases of planned or unplanned low-flow or circulatory arrest.
- The venous reservoir is an extremely important air removal device. Most of the air in the cardiotomy and venous blood flow paths is removed in their respective filtration systems (see Figure 1.7).

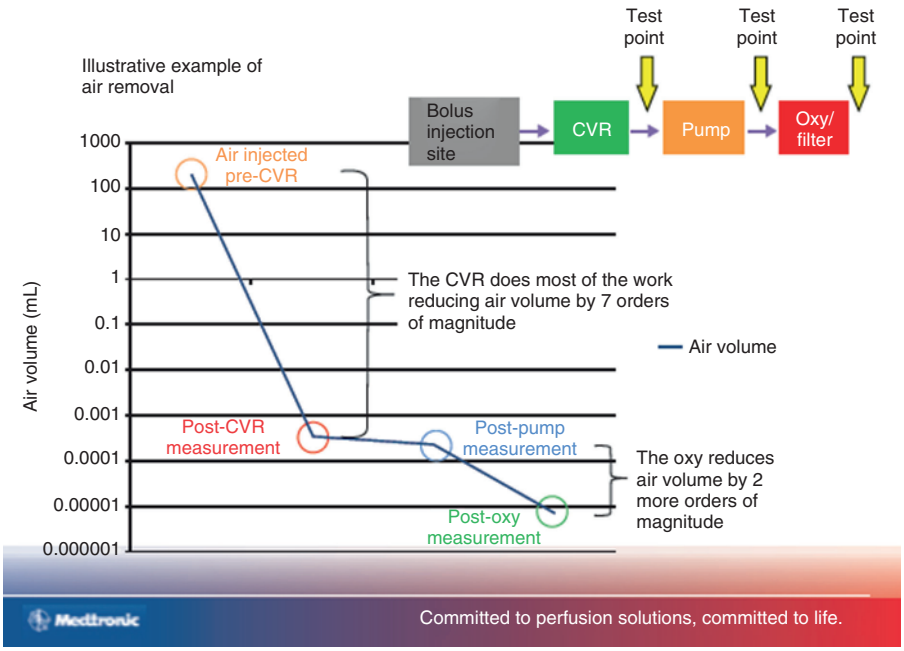


Figure 1.7 Air removal in the CVR, oxygenator, and arterial filter. Reproduced with permission from Medtronic, Inc., Minneapolis, MN. All rights reserved.

- Transit time through a reservoir relates to GME removal since the reservoir works in part by allowing air to rise and exit blood.
- Venous reservoirs have inflows either near the top (top feeders) or bottom (bottom feeders). Both incorporate an extension tube (venous straw) which runs low in the reservoir to help maintain a continuous column of fluid for gravity siphon drainage. The venous straw outlet into the venous reservoir is always below the minimum operating level (MOL) to prevent air from rising into the venous straw.
- Venous filters are normally coated, at least in part, with a chemical compound to help prevent the formation of foam and to eliminate foam that has been introduced to the filter. Antifoam products containing silicone, simethicone, and methylcellulose are currently used for this application.
- The reservoir component of an oxygenator system always has a demarcation line for the minimum operating volume (MOV). This may also be referred to as the MOL. This value is typically set by the manufacturer at the device's maximum rated flow to indicate the level which must be maintained to prevent air entrainment into the blood flow path.
- It is standard of care to place an arterial pump servo-regulating level sensor at or above the MOV on the reservoir's flat vertical surface. Caution must be taken with sloped CVR sections when considering level sensor placement. If the level sensor is placed at the MOV but on the sloped rear surface, this could lead to increased risk for low blood level vortexing and an emptying of the reservoir in conditions where the cardiotomy flow is consistently covering the sloped section. If the perfusionist is not aware of this and chooses to run a relatively

low level in the reservoir, regular aliquots of air may be introduced into the preoxygenator blood flow path. This increases arterial limb GME delivery (even after the arterial line filter) to the patient (9). Note in Figure 1.3 and 1.6 that the venous reservoir surface in the front of the device is vertical, but the drainage of the cardiotomy into the venous reservoir section is sloped. Level sensor placement on the front or side of this device is recommended. Level sensor placement on the sloped surface is neither safe nor recommended.

- Use of a level sensor is listed as Standard 6.3 in the *AmSECT Standards and Guidelines for Pediatric and Congenital Perfusion Practice* (17). The most recent international pediatric perfusion survey indicated that 95% of North American centers were utilizing a level sensor as a safety device (18).
- Some manufacturers, including Eurosets, specify a MOV at different flow rates through the device. This is useful when trying to minimize the need for volume, particularly when weaning from bypass at lower flow rates.

The cardiotomy filter

- The cardiotomy filter has its own flow rating that is generally less than the maximum oxygenator flow but well within the needs for field suction and left ventricular vent flow.
- The cardiotomy filter generally provides more filtering capacity than the venous filter. Venous blood tends to be much "cleaner" with less air and particulate emboli, while cardiotomy blood may have more.
- An integrated cardiotomy filter is typically placed higher than the venous filter. This arrangement allows cardiotomy blood to passively flow into the reservoir after passing through the cardiotomy filter and may reduce the introduction of air into the blood flow path. See Figures 1.1–1.3.
- Consideration should be given to a secondary standalone cardiotomy reservoir if there is concern that the integrated CVR would overflow in cases of pump low-flow or circulatory arrest. The secondary reservoir can be used to temporarily store blood volume.
- A secondary cardiotomy reservoir with filter should also be considered for cases with an expected high sucker flow (reoperations, patients with significant MAPCAs, very large patients with high pump flow, surgery in or around the liver). The additional filtration, or prefiltering, of shed blood provided by a secondary cardiotomy filter may increase the useful life of the primary CVR. When utilized, a secondary cardiotomy is usually set up to process vent and sucker return with drainage to the primary cardiotomy reservoir.
- Cardiotomy filters are normally coated with a chemical compound to help prevent the formation of foam and to eliminate foam that has been introduced to the filter. Antifoam products containing silicone, simethicone, and methylcellulose are currently used for this application.
- Some reservoirs only have defoaming agents coating the upper levels of a reservoir. This results in a system where it is not mandatory for the blood to come into contact with the defoamer. The blood/foam will only come in contact with the defoamer when it is needed (i.e., foam rising above a certain reservoir level during periods of high sucker flow) or when the reservoir level is high. If foam is seen in a CVR during bypass, the perfusionist should maintain a higher reservoir level to aid in the defoaming process. This aids in the removal of GME by contact with antifoam agents and by allowing for an increased reservoir transit time.
- Maintaining an increased reservoir level is also advisable if fibrin or other formations are visible in the cardiotomy venous reservoir.
- Oxygenator–reservoir systems that physically and visually separate the cardiotomy and venous filters are preferred and offer a safety advantage. If a cardiotomy filter becomes compromised (i.e., clot formation due to inadvertent protamine introduction after CPB before suckers are turned off), confirmation of cardiotomy involvement and not venous reservoir involvement is important. If the patient requires additional cardiopulmonary support, CPB can commence, and the perfusionist can add a secondary cardiotomy, with drainage to the venous filter. This adds a considerable safety advantage over the requirement of changing out an entire circuit emergently.

The heat exchanger

- The water flow path in an oxygenator's heat exchanger is commonly referred to as the water phase, whereas the blood flow path is referred to as the blood phase.
- An oxygenator's integrated heat exchanger must be water tested prior to the addition of crystalloid solutions for priming. Running water through the heat exchange system at a flow and pressure *comparable to the operating room values* and inspecting for leaks to the blood phase are important steps in the process of preparing for CPB (4).

- Heat exchangers commonly have water phase pressure limits in the 20–40 PSI range. This far exceeds typical water pressure in a heater-cooler device during normal operation.
- FDA clearance for an oxygenator-integrated heat exchanger includes testing the water phase pressure at 1.5 times the maximum recommended pressure for 6 hours (3).
- Heat exchangers used with recirculating water systems commonly have water phase pressures in the 0–5 PSI range with maximum system pressures <15 PSI. A maximum pressure for a recirculating water flow heater-cooler unit (HCU) may only occur clinically if the outlet water line was acutely kinked or blocked.
- Testing a heat exchanger before bypass with a *defined* positive-pressure water system may help detect water-to-blood leaks due to manufacturing defects.
- Water-testing an oxygenator's heat exchanger using a traditional HCU is not ideal to ensure competence of the heat-exchange material since the water phase pressure in those devices is in the 0–5 PSI range, as mentioned above. A novel method of testing heat exchanger integrity using air has been reported but is not approved by manufacturers, nor reported in their IFUs (19, 20).
- Heat exchangers within oxygenator devices are commonly stainless steel or a plastic polymer such as polyurethane or polyethylene terephthalate (PET).
- Stainless steel heat exchangers do not allow chemicals or medications to transfer from the water into the blood or from the blood into the water.
- Plastic polymer heat exchangers may allow for transference of certain chemicals (i.e., hydrogen peroxide) and medications (i.e., methylene blue) in both directions across the heat exchanger (21).
- The water pathway through an oxygenator helps dissipate static electricity charges that may develop in the roller head pumps and be transmitted through the blood pathway. A metal strip contacting both the water side and the blood side inside the oxygenator serves this purpose. This feature is especially important in preventing static electricity discharge through the heart–lung machine that can cause damage to circuit boards and even the hollow fiber membranes (14, 22, 23).
- Heat exchanger specifications are qualified by a "performance factor" defined as the difference of inlet (venous) and outlet (arterial) blood temperatures divided by the difference of inlet (venous) blood and inlet water temperatures.

$$\text{Performance factor} = \frac{(\text{arterial blood temperature} - \text{venous blood temperature})}{(\text{water inlet temperature} - \text{venous blood temperature})}$$

- The performance factor is frequently in the range of 0.4–0.7 at a device's maximum rated flow. The performance factor and heat exchange efficiency improve at lower blood flow rates and, to some degree, with higher water flow rates.
- The gradient between the venous blood and the water inlet temperature is usually limited to 10°C (though some manufacturers specify a gradient of up to 15°C in their IFU). This is to prevent excessive gradients where there is potential for gas to come out of solution if warmed too rapidly (due to the decrease in gas solubility at higher temperatures). However, an animal study found no correlation between temperature gradient and emboli count (24).
- Temperature gradient control allows for even cooling and warming during CPB.
- The best available CPB guidance suggests that lower temperature gradients may be associated with better neurologic outcomes during rewarming on CPB. A consensus opinion statement supported by AmSECT, the Society of Thoracic Surgeons, and The Society of Cardiovascular Anesthesiologists, recommended that arteriovenous gradients should be limited to 4°C when rewarming above 30°C (25).
- Cerebral hyperthermia with arterial limb temperatures above 37°C has been associated with worse neurologic outcomes (26, 27).
- Hyperthermic temperatures during CPB have also been associated with acute kidney injury (28, 29).
- Considering the risks associated with higher rates of cooling and warming during CPB, the performance factor becomes less important when evaluating a heat exchanger since use at its maximum capacity is rarely warranted or required. Furthermore, an oxygenator is commonly utilized below its maximum blood flow rating (to allow for reserve performance) and therefore the performance factor *at the actual patient blood flow* is often higher.
- It is important to note that there have been oxygenators manufactured with different oxygenator bundle sizes wrapped around the same-sized heat exchanger. Therefore, the perfusionist must be familiar with product line specifications.

- Increased heat exchanger surface area does not always equate to increased performance. The blood flow path through the oxygenator (axial versus radial), the heat exchanger material, and characteristics of the water system will affect performance.
- It is important to consider that the rates of cooling and warming on CPB are impacted by systemic vascular resistance management and pump flow during CPB.
- The heat exchange fluid for most devices is water. Heater-cooler units are most often utilized to cool and heat the water although other systems have been described (30, 31).
- Water-based heater-coolers have been associated with *Mycobacterium chimaera* infections in cardiac surgery patients with significant morbidity and mortality (32, 33). The root cause of these infections is aerosolization of contaminated water from the recirculating water tanks, and not bacterial transmission through the oxygenator's heat exchanger. *See section* ***The Heater-Cooler System*** *below for more information*.
- Spectrum Medical offers standalone heat exchangers that are paired with a glycol-based heat transfer system. This system eliminates the medium whereby bacteria can propagate and then get aerosolized. There are currently three glycol-based heat exchangers approved for CPB temperature control. Table 1.3 shows the Quantum PureFlow standalone heat exchangers and their specifications.

Table 1.3 Spectrum Medical Quantum PureFlow standalone heat exchangers approved for use with glycol-based heat transfer fluid.

	Blood flow rating (LPM)	Prime volume (mL)	Heat exchange surface area (m^2)
Neonatal Quantum PureFlow	1	11	0.028
Pediatric Quantum PureFlow	3	22	0.05
Adult Quantum PureFlow	8	55	0.12

Sweep gas control systems

The CPB oxygenator requires continuous gas flow to allow for gas exchange. This gas flow is commonly referred to as the sweep gas but may also be referred to as the "ventilation," or $\dot{V}$, component through the oxygenator bundle. The blood flow may be referred to as the "perfusion," or $\dot{Q}$ component through the oxygenator bundle. These values are used to determine the ratio between the gas and blood flows through a device, much like the $\dot{V}/\dot{Q}$ ratio used when assessing native cardiopulmonary function. It is essential for the perfusionist to understand the limits for both blood flow and gas flow through a device. Tables 1.1 and 1.2 list oxygenator-manufacturer recommended maximum blood flow rates as well as gas flow limits. Some devices come with a stated maximum gas flow (i.e., up to 12 LPM) whereas others have stated maximum $\dot{V}/\dot{Q}$ ratios (i.e., max 2:1). Some devices list both. Further, manufacturers may clarify separate ventilation and perfusion parameters when an oxygenator bundle is suspected of being wetted-out. That phenomenon may be the result of increased condensation in the gas flow path, and so a higher gas flow rate or $\dot{V}/\dot{Q}$ ratio may be used to clear the condensation. This technique may be referred to as "sighing the oxygenator membrane." Manufacturers may also specify minimum gas flow rates through a device. This minimum is aimed at ensuring the oxygenator bundle fibers are fully utilized for gas exchange as low gas flow rates may result in $\dot{V}/\dot{Q}$ mismatch where there are portions of the oxygenator with blood flow but not gas flow.

Perfusionists must be cognizant of sweep gas system flow limits, particularly for the carbon dioxide gas flow. This is of particular concern during pH-stat blood gas management with the low pump flow rates seen in neonates and infants (4). The minimum CO_2 flow in essence limits the lower limit of overall blended gas flow. For example, during regional perfusion at 30 mL/kg/min on a 3.3 kg neonate, the pump flow would be 100 mL/min. If the minimal CO_2 flow through the EGB is 20 mL/min, the blended gas flow may need to be 300 mL/min to maintain the $PaCO_2$ at its desired level. Turning off the CO_2 flow may result in a $PaCO_2$ that is too low, even with the blended gas flow at its minimum flow setting. This results in a situation where the ventilation to perfusion ratio with CO_2 in use may exceed the manufacturer's recommended limit of 2:1. In this example, it would be 3:1. The perfusionist must be familiar with the oxygenator manufacturer's recommended limits, if any, for $\dot{V}/\dot{Q}$ ratio during CPB. For decades, manufacturers have tested their devices up to a $\dot{V}/\dot{Q}$ ratio of 2:1, likely because there was little identified need to exceed that limit. Low flow and regional perfusion strategies in congenital cardiac surgery are just two examples where this limit may need to be exceeded. Ideally, the neonatal and infant oxygenators in use in a perfusion practice allow for these higher $\dot{V}/\dot{Q}$ ratios (4).

Sweep gas control for congenital heart surgery patients at the most basic level involves a mixture of 100% oxygen and medical grade air that can have 100% CO_2 added in. Sweep gas is controlled by traditional gas flow meters or electronic gas blenders. Electronic gas blenders have come into favor over traditional flow meters because of the precision and safety they afford the user. For example, while the air and oxygen mix may be in the range of traditional flow meters, the carbon dioxide flow rate is typically lower than what most flow meters can consistently achieve. This is a safety concern since a small increase in the 100% CO_2 flow can result in dangerously high $PaCO_2$ levels.

All HLM systems should *measure* the oxygen percentage delivered to the patient. The oxygen analyzer may be integrated into the HLM or be a separate device. Use of an oxygen analyzer for the sweep gas is listed as *Standard 7.9* in the AmSECT *Standards and Guidelines for Pediatric and Congenital Perfusion Practice* (17). Even with this guidance, the latest available pediatric perfusion worldwide survey indicated that only about 60% of European centers and 50% of northern North American centers abided by the standard. All other survey regions reported lower usage (18).

Two manufacturers that currently offer electronic gas blending are LivaNova (London, UK) and Spectrum Medical (Gloucestershire, UK). LivaNova has three separate devices that vary only in the gas flow ranges and level of precision. They offer their *Electronic Gas Blender* in 10 LPM, 5 LPM, and 2 LPM versions. Those values refer to the air/oxygen sweep gas maximum flow rates, exclusive of the CO_2 flow rate. Intuitively, the 10 LPM version offers the most range and seems ideal but the resolution for flow control is less precise. That is why two other versions are offered. The sweep flow precision values for each device are 10 LPM (0.1 LPM), 5 LPM (0.05 LPM), and 2 LPM (0.02 LPM). All offer carbon dioxide flow rates of 0.2–1.0 LPM. The 2 LPM version is important for precise blood gas control in neonates and infants undergoing hypothermic CPB with pH-stat blood gas management (*see Blood Gas Management in Chapter 3, The Cardiopulmonary Bypass Plan*). The 2 LPM *Electronic Gas Blender* works exceptionally well for congenital heart surgery cases when paired with a traditional flow meter. Pairing with a traditional flow meter on a manual gas blender source allows for higher overall sweep gas flow rates while still maintaining the CO_2 flow precision down to 0.02 LPM (20 mL/min). This high gas flow capability is important for larger patients and when there is a need to treat a wetted-out oxygenator.

Spectrum Medical offers a Quantum ventilation system (QVS) that has seen upgrades over the past several years. Their electronic gas blending system allows for precise oxygen and carbon dioxide flow control over a wide range of overall sweep gas flow rates (20 LPM overall but qualified as 10 LPM if utilizing 100% oxygen). Their CO_2 flow precision is reported at 1 mL/min. The QVS goes beyond the functionality of an electronic gas blender system, though. Their system offers sweep gas line pressure monitoring as well as optional automation features. Every oxygenator IFU states that the gas phase pressure must never exceed the blood phase pressure in order to prevent air emboli from entering the blood through the microporous membrane oxygenator. Unfortunately, details on when this may become a real consideration are lacking in the literature and from manufacturers (4). Their system measures the gas line pressure going into the oxygenator and alerts the perfusionist when the value exceeds approximately 50 mmHg. This is an important advance for patient safety. Additionally, the QVS provides the option to set target trending PaO_2 and $PaCO_2$ values, as measured by a proprietary noninvasive technology, with the ventilation module adjusting the sweep gas accordingly.

Arterial line filters

The CPB circuit contains filters in several systems: the cardiotomy reservoir, venous reservoir, oxygenator bundle, bypass arterial line, prebypass, gas line, crystalloid line, blood transfusion line, cardioplegia system, and others. The ALF tends to receive the most attention since it serves as the last system in a CPB circuit to trap and/or remove particulate and air emboli from the blood before return to the patient. It is important to note that one of the most important aspects of a bypass circuit is its ability to remove (and not create) particulate and air emboli. Numerous studies have conclusively shown that GME are delivered to patients on bypass (9, 34–39). These emboli can result in microvasculature blockages with the downstream effects of hypoperfusion and ischemia. Thus, minimization, and ideally elimination, of GME during cardiac surgery with CPB is important to improve postoperative neurologic outcomes for patients (40–43). Air in particular is disruptive to the endothelial glycocalyx which has important implications for vascular permeability and the potential for edema throughout the body with CPB (44, 45). Adoption of an ALF by worldwide regions ranges from 90% in Asia to 98% in northern North America (18).

The ALF is a screen filter with a pore size generally in the 25–40 μ range. Filtration may occur in the oxygenator itself with novel bundle wrapping technology, with a screen wrapped around the oxygenator bundle, or with an external filter either directly attached to the oxygenator device or connected downstream via tubing. The ALF must have its surfaces wetted and then be properly deaired with a crystalloid priming solution before bypass. If a blood prime is used, blood should only be added after crystalloid priming and thorough ALF deairing.

- External ALF screen filters are either flat sheet membranes or folded membranes. Folded membranes have more surface area and allow for higher rated flow rates for a given filter pore size. Table 1.4 lists specifications for external ALFs currently available.
- The Medtronic Affinity Fusion utilizes novel oxygenator bundle wrapping technology to filter the arterial blood before return to the patient. This device is rated to 25 μ for filtration (46). GME removal with oxygenator bundle wrap filtration, without an external ALF, has been shown to be less efficacious than other ALF technologies (35).
- The Terumo CAPIOX FX Advance series of oxygenators includes a 32 μ screen filter wrapped around the oxygenator bundle to serve as the ALF (47). Oxygenator-wrapped screen filtration has shown similar GME removal efficiency when compared to standalone ALFs (48). Of interest, the "CAPIOX" term was coined by Terumo as the portmanteau of "*capillary*" and "*oxygenation*."
- An oxygenator-integrated ALF should not be used above the manufacturer's maximum flow rating, even if gas exchange is acceptable, without manufacturer's confirmation that the filter can safely handle a higher flow since the transmission of GME may increase and be associated with adverse neurologic outcomes. Pushing a device beyond its rated flow is off-label use and introduces patient safety and ethical concerns (8).
- The Livanoa Inspire® oxygenator line offers a standalone 38 μ ALF attached to the oxygenator housing with a filter purge line (49).
- External ALFs filter blood for particulate matter and GME. Particulates greater than the rated pore size are typically caught in the screen mesh. GMEs are ideally purged through one of two mechanisms. Most ALFs have a purge line attached to the top of the device that allows for continuous blood flow back to the CVR during CPB. This blood flow conveys any included GME back to the cardiotomy portion of the reservoir for further filtration. The other GME purge system is the auto-venting type. With this technology, the top of the ALF has a hydrophobic membrane which allows gas bubbles to exit to the atmosphere. There are no auto-venting external ALFs on the market at this time.
- Arterial filter housing shape and the throughput blood flow rate both impact air removal efficiency (50).
- Arterial filter purge line blood flow rate is an important consideration for GME removal for devices using that technology. Higher flow rates and system pressures decrease GME removal efficiency (51).
- Arterial filter purge line flow steals from effective systemic perfusion flow (52, 53). An arterial line flow probe must be used after all possible arterial shunts to monitor true blood flow to the patient. This is qualified as Standard 7.3 in AmSECT's *Standards and Guidelines for Pediatric and Congenital Perfusion Practice* (17).
- External ALF housings are preferably clear to visually facilitate deairing during crystalloid priming.
- External ALFs most commonly have folded or wrapped filter medium that is not fully visible. The filter should be carbon dioxide flushed prior to crystalloid priming (54). Then, with fluid flowing through at the manufacturer's recommended rate for priming, the filter should be adequately tapped to ensure no air is trapped (more precisely, any microbubbles present *should be* carbon dioxide if CO_2 flushing is performed before priming).

Table 1.4 External arterial line filters.

Manufacturer	Model	Maximum flow (LPM)	Pressure drop at max flow (mmHg)	Pore size (microns)	Prime volume (mL)	Construction	Contact surface area (cm^2)
Sorin	D 130 Kids 40 μ Neonatal	0.7	5	40	16	Flat sheet	11
Sorin	D 131 Kids 40 μ Infant	2.5	35	40	28	Flat sheet	27
Sorin	Micro 40 μ Infant	2.5	60	40	47	Folded membrane	150
Sorin	Micro 40 μ Small Adult	5	30	40	100	Folded membrane	340
Sorin	Micro 40 μ Adult	7	45	40	195	Folded membrane	655
Medtronic	Affinity AF 100	7	36	30	100	Folded membrane	290

Cardiopulmonary bypass tubing and custom packs

Custom tubing packs for CPB circuits are created by the perfusion team to aid in quick and efficient setup of the HLM. A congenital cardiac program may have 3–5 different oxygenators as well as 3–5 standard tubing packs. These primary packs may include options for the arterial boot tubing as well as ultrafiltration options (active versus passive ultrafiltration, option for modified ultrafiltration, etc.). This creates numerous available combinations. Table 1.5 is offered as an *example* of tubing pack components and prime volumes across the CPB flow requirement spectrum. The maximum flow rate anticipated on bypass is identified on the left with prime volumes and circuit components required listed in the middle. The last column on the right lists the limiting factor requiring component upsizing, with an obligatory increase in the prime volume. *See Chapter 13, Consolidated Experience-based Equipment Selection Charts for Cardiopulmonary Bypass*, for an example of a quick-reference overall equipment selection guide for a perfusion team.

- A cardiovascular team must define their maximum acceptable flows through the various sizes of available tubing: 3/16″, 1/4″, 3/8″, and 1/2″ (other sizes are available but are less commonly used).
- Tubing used for venous return may be evaluated with gravity versus augmented drainage.
- Venous drainage is nearly always with a single piece of tubing although there are practices which have adopted dual venous lines for specific purposes (55, 56).
- Institutions vary in regard to standard bypass tubing length to the surgical field, patient table height, venous reservoir height, the use of augmented venous return, and typical venous cannulae style and size which all impact achievable flow rates.

Table 1.5 Example of equipment selection matrix based on anticipated maximum pump flow rate.

Flow Range for Tubing Pack (LPM)	Total circuit prime, excluding hemoconcentrator (mL)	Oxygenator and ALF	Primary tubing pack components	mL of prime for oxygenator (O), reservoir (R), arterial limb (A), boot (B), venous limb (V), centrifugal venous head and tubing (CH), (ALF) external arterial line filter	Limiting factor requiring component upsizing
Up to 1.2	215	Terumo CAPIOX FX05 rated to 1.5 LPM; integral 32 μ ALF	3/16 arterial, 3/16 boot, 1/4 venous	(O) 43, (R) 75, (A) 30, (B) 15, (V) 52	3/16 arterial line max flow 1.2 LPM at 162 RPM
1.2–1.4	230		3/16 arterial, 1/4 boot, 1/4 venous	(O) 43, (R) 75, (A) 30, (B) 30, (V) 52	1/4 venous line max 1.4 LPM with gravity drainage
1.4–2.1	420	Sorin D101 rated to 2.5 LPM paired with 40 μ D131 external ALF	1/4 arterial, 1/4 boot, 3/8 venous	(O) 87, (R) 100, (A) 60, (B) 30, (V) 115, (ALF) 28	Integrated cardiotomy venous reservoir performance limited to 2.1 LPM based on team experience
2.1–3.15	570	Terumo CAPIOX FX15-30 Advance rated to 5 LPM; integral 32 μ ALF	1/4 arterial, 3/8 boot, 3/8 venous	(O) 144, (R) 150, (A) 75, (B) 65, (V) 136	1/4 arterial line max 3.15 LPM
3.15–3.6	660		3/8 arterial, 3/8 boot, 3/8 venous	(O) 144, (R) 150, (A) 160, (B) 65, (V) 141	3/8 venous line max 3.6 with gravity drainage
3.6–4.4	730		3/8 arterial, 3/8 boot, 3/8 venous, centrifugal venous assist head	(O) 144, (R) 150, (A) 175, (B) 65, (V) 141, (CH) 75	3/8 boot to 4.4 LPM at 157 RPM
4.4–5	760		3/8 arterial, 1/2 boot step up, 3/8 venous, centrifugal venous assist head	(O) 144, (R) 150, (A) 175, (B) 90, (V) 141, (CH) 75	Oxygenator max rated flow 5 LPM
5.0–7.0	950	Terumo CAPIOX FX25 Advance rated to 7 LPM; integral 32 μ ALF	3/8 arterial, 1/2 boot step up, 3/8 venous, centrifugal venous assist head	(O) 260, (R) 210, (A) 175, (B) 90, (V) 140, (CH) 75	N/A

- Regardless of where in the circuit a piece of tubing is being utilized, if flow through it is dependent on a roller head pump, the occlusion setting for that pump with the specific tubing size through it must be done before every case. This is commonly a prebypass checklist item (see checklists for cardiopulmonary bypass in *Chapter 3, The Cardiopulmonary Bypass Plan*).
- Boot (arterial pump raceway) tubing should be evaluated for flow based on head RPMs since spallation and the potential for failure are a function of the number of tubing compressions over time. Maximum RPMs used are commonly in the 160–170 RPM range even though roller heads may be capable of 250 RPMs.
- Smaller raceway lengths (i.e., mini-heads) increase the compression rate for a given pump flow rate.
- Table 1.6 outlines an *example* of the maximum flows used for various tubing sizes.
- Table 1.7 identifies tubing prime volume per foot of length.
- A primary objective in defining custom tubing pack components is to achieve the smallest prime volume while ensuring adequate and safe flow rates and pressures throughout the CPB circuit.
- Consideration must be given to the range of operative table movement since rolling the bed away in an up position may require several inches of arterial and venous pump tubing to safely accommodate.
- The venous line must have some slack in it to allow for "walking" air out if an air lock develops on bypass with gravity siphon drainage.

Table 1.6 Typical tubing sizes with maximum flow.

Tubing size	Max flow boot line in standard raceway (mL/min)	Max flow arterial line (mL/min)	Max flow venous line with gravity siphon drainage (mL/min)	Max flow venous line with assisted drainage (mL/min)
3/16″	1,200	1,500	600	800
1/4″	2,100	3,150	1,400	2,000
3/8″	4,400	>3,150	3,750	>3,750
1/2″	>4,400	NA	>3,750	>6,000

Table 1.7 Circuit tubing prime volume.

Internal tubing diameter	1/8″	3/16″	1/4″	5/16″	3/8″	1/2″
Milliliters per foot	2.4	5.0	9.7	15.5	21.7	38.6

- Universal use of vacuum-assisted venous drainage in a practice allows for decreased priming volumes since the oxygenator assembly can be moved closer to the patient. Gravity drainage requires the assembly to be closer to the floor for sufficient kinetic potential.
- Tubing utilized for a left ventricular vent or aortic root vent most commonly has a one-way valve incorporated into it. This valve typically serves two primary purposes. First, it prevents massive air embolism into the patient's arterial circuit if tubing is placed in a pump head backwards or if the direction of rotation in the pump head is set incorrectly. Second, it may limit the overall vacuum level transmitted so as not to harm the tissue or muscle in the aorta or left ventricle (or left atrium). Use of a one-way valve in the left ventricular vent line is listed as Standard 6.6 in the AmSECT *Standards and Guidelines for Pediatric and Congenital Perfusion Practice* (17). The most recent international pediatric perfusion survey indicated that 88% of North American centers utilized a one-way valve in the venting line (18). See *Chapter 18, Perfusion Standards for Congenital Heart Surgery*, for a complete list of safety devices included as standards of care.
- Tubing used as pump/field suctions or "pump suckers" may also utilize one-way valves for increased patient safety. These valves can be incorporated on the sterile field as part of a custom tubing pack or off of the surgical field closer to the perfusionist where the device can be monitored more directly.
- The total system prime volume will include the tubing pack, oxygenator, external ALF (if required), and the starting reservoir level. This is the prime volume that will become part of the circulating blood volume once the patient is placed on support.
- The hemoconcentrator prime volume is an additional consideration for overall prime volume but is not typically part of the obligate circulating blood volume during CPB. Rather, it is an optional circuit that can be utilized only as needed. Further, hemoconcentrator volume may be recovered before termination of CPB if modified ultrafiltration will not be performed.
- Tubing lengths will vary for each case based on how much of the arterial-venous loop is discarded before connection to the bypass cannulae. Excess tubing in the pack is important to accommodate varied pump positions, particularly variances for femoral bypass.
- Tubing placed in roller head raceways may develop "memory" if left occluded for an extended period of

time. For this reason, many centers leave the tubing out of the raceway until the priming process.

- Some pediatric centers qualify a much lower prime volume with the use of retrograde arterial priming and venous antegrade priming. It is debatable whether these autologous priming strategies have a net positive effect since young congenital heart disease patients frequently do not have much volume to "donate" to the bypass circuit in the immediate prebypass period. In fact, these patients are frequently more sensitive to overall volume loss during cannulation. Further, these techniques commonly require phenylephrine to maintain hemodynamics and it is undecided if increasing the systemic vascular resistance immediately before cooling on CPB is advisable.
- The prime volume of a custom tubing pack is simply the various line lengths multiplied by the volume contained (plus the oxygenator and reservoir volume). The volume of tubing cut off at the field may be subtracted only if it is accounted for with the starting reservoir level since blood-primed circuits will have this volume returned via the pump suckers before bypass.
- Tubing for CPB is most often coated with a surface-modifying agent that decreases platelet activation and the inflammatory response. While strong evidence that these surface-modifying agents alone improve cardiac surgery outcomes is lacking, they are likely beneficial when combined with other techniques to minimize the negative sequelae of CPB (57).
- Clinicians must be cognizant of the differences in tubing grip strength to a circuit component when considering surface-modifying agent type, tubing manufacturer brand, oxygenator brand, and connector brand. There are important measurable differences in grip strength between the varying combinations (58, 59). Recognition of these differences should help prevent circuit disconnects and associated patient safety issues.
- Approximately 95% of pediatric cardiac surgery centers in the United States and 41% of international centers utilize CPB tubing with a surface-modifying agent (18).
- The arterial limb of a CPB circuit will commonly have bubble detector safety device incorporated. This device is designed to detect large gaseous emboli and to immediately turn off the arterial pump to prevent an air embolism in a patient. Use of a bubble detector is listed as Standard 6.2 in the AmSECT *Standards and Guidelines for Pediatric and Congenital Perfusion Practice* (15). The most recent international pediatric perfusion survey indicated that the majority of centers around the world utilize a bubble detector in their circuits, but placement varies (18). While ideal placement would be on the arterial limb after all connections and shunts in a circuit, perfusionists must also consider how a circuit gets set up on an HLM and practical matters for its incorporation, which drives placement decisions.
- The perfusion team is encouraged to have a check-off sheet for completed tubing pack set-ups that are not immediately utilized. A check-off system ensures that one member of the team reviews the set up for completion and that all connections are appropriate, per team standard. This is important as other team members may be required to use a circuit urgently.

The heart–lung machine

The HLM serves as the foundation of extracorporeal support. It is a machine that incorporates numerous pump heads along with control and monitoring systems for these pumps. The primary changes in HLMs over the past decade have been the increased use of "smart systems" integrated into the HLM computer system along with a move towards mast-mounted pump heads. The HLM has evolved over the decades and while there are only a handful of large-scale manufacturers for them, there are still no clinical standards in terms of the number of individual pump heads or their arrangement on a console base.

This increased computerization, or use of "smart-systems," has been driven by the desire to monitor goal-directed initiatives in real time during surgery, as well as data analytics for retrospective analysis (60–62). Goal-directed perfusion parameters often require complex calculations, not practical to manually perform during surgery. For example, one of the most utilized goal-directed perfusion parameters is indexed oxygen delivery. Research with indexed oxygen delivery during both CPB and the immediate postoperative period has shown inflection points for risk of acute kidney injury (AKI) as well as overall outcomes (63, 64). The calculation for indexed oxygen delivery (iDO_2) during CPB is as follows:

$$\begin{aligned} iDO_2\,\mathrm{mL/min/m^2} = [&(\mathrm{Hgb\,g/100\,mL} \times 1.34 \\ &\times \mathrm{Hgb\,saturation/100}) \\ &+ (0.003\,\mathrm{ml\,O_2/100\,mL/mmHg} \\ &\times \mathrm{PaO_2\,mmHg})] \\ &\times [\mathrm{Cardiac\ Index\,L/min/m^2}] \times 10 \end{aligned}$$

*See *Blood Flow Rate during CPB* in Chapter 3 for more detailed information

While the manual calculation of this *may* be manageable during CPB, real-time calculation by the HLM computer and instantaneous second-to-second display on the HLM is much more practical. Furthermore, while iDO_2 itself is important, the dose response to values below a user-defined critical threshold (i.e., the area under the curve) is likely even more critical (65, 66). The use of real-time monitoring of iDO_2 is just one calculated parameter displayed on the HLM, which may help improve outcomes. Several other calculations are also utilized and these too require integration of CPB parameter data, blood gas analysis data, near infrared spectroscopy values, and patient-specific parameters (67, 68). These initiatives aim to improve outcomes by monitoring variances in real time, which affords the clinician an opportunity to intervene in a meaningful way during actual patient care.

One other primary change with HLMs over the past decade is the move towards all mast-mounted heads. This change has allowed programs to customize their HLM set up to a high degree. This customization is commonly aimed at minimizing circuit volume by moving pump heads closer to the surgical field. Mast mount heads may also be easier to change in the event of a head failure, thus increasing overall system safety.

The primary HLMs currently in use are the LivaNova Essenz, the Spectrum Medical Quantum, LivaNova S5 (standard and PRO versions), Medtronic Century, and the Terumo Advanced System 1. While Essenz and the Quantum are the latest generation of HLMs with the most computerization, clinicians may purchase data management HLM computers as standalone devices or utilize an integrated hospital-based electronic health record to obtain the benefits of monitoring goal-directed perfusion parameters.

It is essential for patient safety that HLMs are maintained by qualified biomedical engineering personnel and/or manufacturer technicians. In fact, in the United States, it is a condition of participation for federal reimbursement programs such as Medicare and Medicaid that hospitals prove compliance with the conditions for participation (69). This can be achieved with successful passing of an on-site survey by the Joint Commission or the Centers for Medicare and Medicaid. In a practical sense, this means that perfusion programs must maintain their HLMs (and all clinical care machines) per manufacturer guidelines. This most often requires an annual preventative maintenance service for each HLM. Failure to maintain this compliance schedule requires removal of the HLM from service. The Health Technology Management (i.e., Biomedical Engineering group) ensures compliance with these regulations.

Arterial pump options

HLMs for congenital heart surgery most often use roller heads for the arterial pump. Roller head pumps allow for precise control of blood flow and are not afterload sensitive. Centrifugal heads are less commonly used for congenital cardiac surgery, especially in younger patients. Centrifugal heads may have theoretical advantages in regard to decreasing blood trauma and preventing massive air infusion, but studies have shown that centrifugal heads can produce more hemolysis than roller pumps and they transmit gaseous microemboli just as roller heads do (70–72). However, the inability to finely control blood flow for extended periods of time, especially when weaning support, and the inability to provide exceptionally low blood flow rates for neonates or during regional cerebral perfusion, essentially limit their utility in congenital cardiac surgery. Additionally, it is less than ideal to have a perfusion group switching between roller heads and centrifugal heads depending on the day's case mix and having more custom pack options on the shelf to accommodate such. Therefore, most congenital cardiac surgery programs utilize roller head pumps in the arterial position on their HLMs.

The heater-cooler system

The heater-cooler system is an essential CPB component. It is the piece of hardware that allows for patient and cardioplegia temperature management during CPB. A heater-cooler system comes in three varieties: water-based mobile units, glycol-based mobile units, and water-based infrastructure systems.

The most common systems are water-based mobile units. The LivaNova 3T™ Heater-Cooler System is one example, and this device is capable of heating and cooling up to three water baths (Figure 1.8). One water bath is connected to the oxygenator heat exchanger with water lines capable of providing 10–18 LPM of water flow and temperatures of 15–41°C. The other water bath(s) are generally used to provide temperature management to the cardioplegia system. These baths allow for intraoperative transition between cardioplegia strategies: cold (2–15°C), tepid (28–32°C), and warm (32–37°C). The CardioQuip MC-1000 line of heater-coolers is another example of a water-based heater-cooler system (Figure 1.9). This device includes two tanks for individual patient-temperature and cardioplegia-temperature management. There is a 1,600 W heating element along with two options for cooling:



Figure 1.8 The LivaNova 3T™ Heater-Cooler System with add-on vacuum module for scavenging air from system cooling fans. Used with permission by LivaNova PLC (London, UK).



Figure 1.9 CardioQuip MC-1000(i)water-based heater-cooler system. Used with permission by CardioQuip (College Station, TX).

user-provided ice or an integrated refrigeration unit. Water flow through the system is rated at 14–20 LPM, and the water temperature ranges from 3 to 42°C.

A water-based heater-cooler unit is a rather simple device. It provides water flow based on pump power and system resistance. Different oxygenators and different water connection lines, lengths, and hardware will result in varying water flow rates. While water flow rates of 10–18 LPM are commonly used by manufacturers to test oxygenator heat exchangers, most devices do not provide water flow readings to clinicians (4). If a flow quantifier is not included with the unit, an aftermarket product should be added. It is important to have the ability to monitor water flow since it contributes to heat-exchange efficiency. The ability to readily quantify water flow is important when ruling out issues related to the temperature management of a patient. Suboptimal water flow, due to a kinked line, for example, can significantly decrease the ability to properly manage a patient's temperature on bypass.

Water-based heater-cooler systems remain the most commonly utilized systems for cardiac surgery, as all CPB oxygenators currently on the market are only approved for use with water as the heat-exchange medium. Unfortunately, water-based systems carry significant risks for patient infection. Water-based systems recirculate water at varying temperatures and may serve as a medium for bacterial growth that is difficult to eradicate (73, 74). While the water in these systems never comes into contact with the patient or the patient's blood, aerosolization of contaminated tank water has led to morbidity and mortality in patients across the globe (32, 33, 74). Recognition of this significant patient safety risk has led hospitals to review their operating room ventilation systems as well as positioning of heater-cooler units relative to the sterile surgical field (75, 76). These are exceptionally important considerations since eradication of bacteria from recirculating water tanks, and thus patient risk of infection, is challenging and not guaranteed (77). The LivaNova 3T™ Heater-Cooler System now comes standard with a vacuum module on the heater-cooler housing to capture system cooling fan flow. This modification decreases the risk of aerosolization in the operating room and the risk of interrupting the operating room air flow curtain (76).

Hospitals and industry have responded to this patient-safety crisis for cardiac surgery patients with unique alternatives including glycol-based mobile units and hospital-infrastructure-based systems. Spectrum Medical was the first manufacturer to release a mobile CPB

heat-exchange system that was not based on water as the heat-exchange medium. Their Quantum Heater-Cooler, also known as Mr. Frosty, utilizes ethylene glycol as the heat transfer fluid paired with disposable heat exchangers inserted into the CPB tubing set. This system both eliminates the growth medium of water and removes the hardware cooling fan. Removing the fan is an important consideration since it prevents the heater-cooler from disrupting the operating room's air flow curtain ventilation system. The major disadvantage of their system, particularly with pediatric cases, is the requirement to increase circuit prime volume with the addition of a standalone heat exchanger. Table 1.3 lists the additional prime volume added to a circuit based on blood flow capacity requirements. Further, the glycol heat exchange fluid requires regular cold energy recharging, and this may impact efficiency during long hypothermic cases requiring exchanging the base unit out with a fully charged backup. Finally, ethylene glycol has a useful lifespan and must occasionally be exchanged. This must be considered for device fleet management and rotation in larger practices with multiple units. Regardless, glycol-based systems have been shown to be substantially equivalent to water-based settings in terms of heat exchange capacity and represent an important option to improve patient safety by eliminating the risk of infection associated with water-based units (78).

There are currently two water-based infrastructure systems in use for cardiac surgical cases: the Boston Children's Hospital (BCH) wall water system and the HCTronic Heater-Cooler System. The BCH wall water system was engineered on short notice after the United States Centers for Disease Control and Prevention recommended that cardiac surgery centers discontinue use of Stöckert 3T heater-cooler units (now LivaNova PLC, London, United Kingdom) in October 2016 (30). This system was a re-engineering of a "wall water" system that had been in use from the 1970s to 2010. Hospital infrastructure already supported the independent water heaters and chillers dedicated to CPB temperature management. The new system added important safety and control elements. Figure 1.10 shows a schematic of the elements for the wall water system. The hot and chilled water supply, along with a system-drainage holding tank, are located on a lower floor of the hospital. These water supplies are piped to the cardiac surgery floor and independently feed each operating room's mixing valve, located in the hallway. The perfusionist controls water temperature and flow to the oxygenator heat-exchanger via a boom-mounted control panel next to the HLM. This system has the advantage of eliminating the recirculating water tank from the operating room while allowing for safe use of water-based heat exchange. Moreover, it eliminates the risk of aerosolization and infection caused by heater-cooler unit system fans. The BCH wall water system also eliminates daily or weekly maintenance tasks for the perfusion team. Heater-cooler maintenance for safety concerns can require several hours of perfusionist labor each week. The wall water system requires maintenance, and this is primarily done by hospital's facilities management team. Disadvantages include overall system cost, space and plumbing requirements, and the lack of industry support with specialized technicians. Furthermore, this system only provides one water source to the operating room. BCH had long utilized ice for cooling a cardioplegia system coil and so this was not an issue. Other programs would be required to have a separate cardioplegia heater-cooler or separate wall water lines dedicated to cardioplegia temperature management. Finally, this system nearly instantaneously provides the requested temperature since it utilizes a mixing valve and there is not a requirement to independently heat or cool a recirculating water tank, as with standalone heater-cooler units. This is an advantage in terms of efficiency, but users must be careful when setting the temperature on the remote control since rapid and excessive temperature gradients during CPB are known to carry risk, as discussed in the temperature management section of *Chapter 3, The Cardiopulmonary Bypass Plan*. Failure mode backup for this system includes use of either traditional heater-cooler units or patient-blanket units with water line adapters allowing connection to the oxygenator heat exchanger.

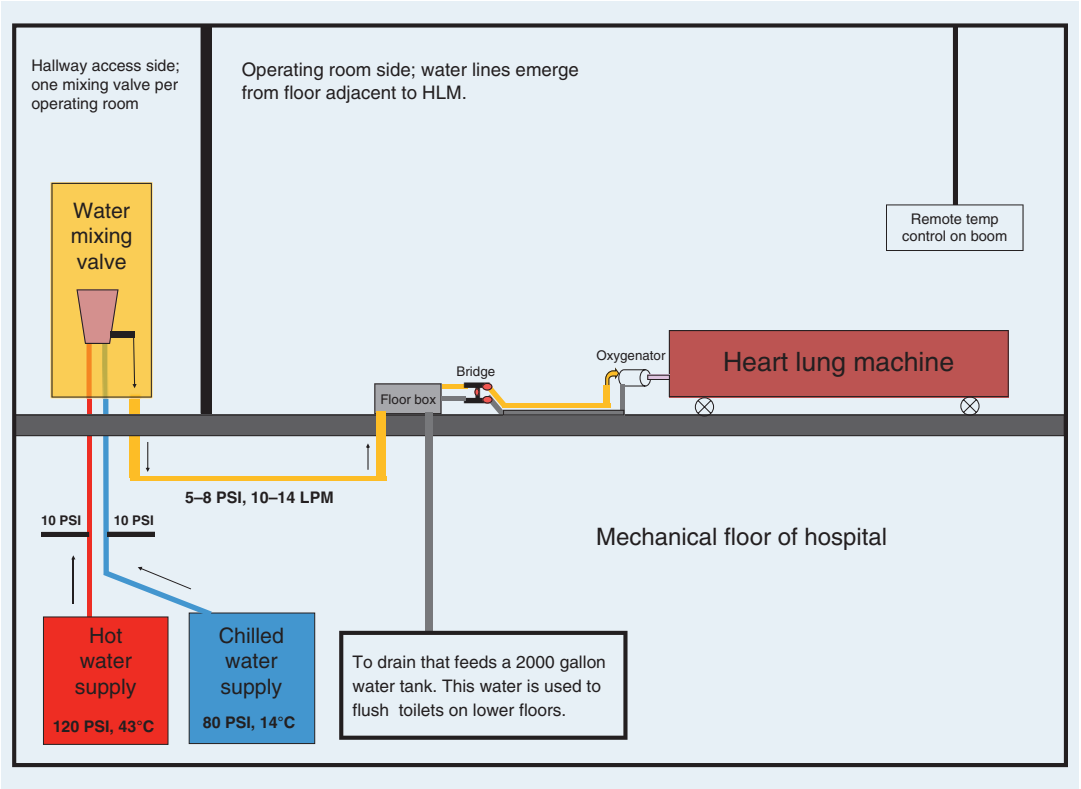


Figure 1.10 The Boston Children's Hospital wall water system for CPB heat exchange.

One other water-based infrastructure system for CPB heat exchange is the HCTronic Heater-Cooler System (Waardenburg, The Netherlands). This novel system moved the water reservoir out of the operating room and eliminated any cooling fan in the operating room, which could interrupt the air flow curtain (31). Fresh filtered potable water is added to the system before each use. Their system requires space on the cardiac surgical floor to house the mechanical and control systems for heating, cooling, and disinfecting the water within the system. Water lines connect from the primary system components, through the operating room walls, to hookups on the wall in each operating room. The perfusionist attaches water lines to the oxygenator heat exchanger in the standard fashion, as shown in Figure 1.11. Two other water circuits are available for cardioplegia heat exchange or another user-defined need. This system is essentially a larger heater-cooler unit located outside of the operating room. It allows for complete emptying of the water lines after each case with medical-grade air purging of the water lines, ensuring the system is ready for fresh water for subsequent use. This system also has the advantage of an automated heat-based disinfection cycle. This system is less costly than the BCH wall water system with a significantly smaller footprint requirement within a hospital. Disadvantages of all infrastructure-based water systems are that they require physical plant space in the hospital and the startup costs are greater than standalone units.

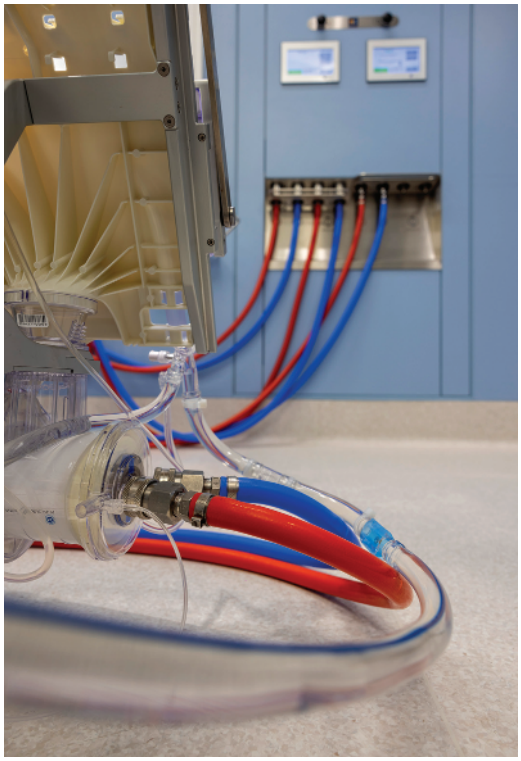


Figure 1.11 HCTronic Heater-Cooler System wall water lines hooked up to the oxygenator heat exchanger.

Next generation heater-cooler units

Water-based heater-cooler systems remain as the only systems approved for use with oxygenator-integrated heat exchangers. Manufacturers continue to develop the next generation of devices, including standalone water-based units. These next-generation devices will need to effectively provide intraoperative heat exchange while eliminating the aerosolized infection risk, which impacted cardiac surgery patients around the world in the recent past.

Lauda Medical (Lauda-Königshofen, Germany) has developed a next-generation cardiac surgery heater-cooler system called the HYPO. The Lauda Medical HYPO is shown in Figure 1.12, but it is not currently available for purchase as it is in the approval process with the United States FDA and other medical device oversight organizations. Nevertheless, the design features of this device are innovative and address concerns with current water-based standalone systems. The physical space requirements, temperature range specifications, and compatibility with current oxygenator heat exchangers on the market will likely lead to a low adoption threshold for clinicians, once the device is approved for use.



Figure 1.12 The Lauda Medical HYPO heater-cooler unit for cardiac surgery. Note: device is pending approval for use and is not currently available on the market.

Two key features of the HYPO heater-cooler unit are that it utilizes an endotoxin-free water-based solution, and this fluid is contained in a disposable sealed fluid circuit. This recirculation fluid is purchased separately and eliminates the need for hospitals to have dedicated fill station locations. This also removes the need to purchase water filters and tubing for the HCU fill station. The disposable circuit includes the tubing lines with sterilizable self-closing quick connects for attachment to the oxygenator and cardioplegia heat exchanger. The disposable tubing set component provides for a closed-circuit architecture with filtration to 0.2 µ. The HYPO also has ultraviolet light disinfection internal to the unit. The disposable tubing set is expected to be qualified for 30 days of use. LivaNova (London, UK) will be the official distributor for the HYPO heater-cooler.

Cannulae

Patients with congenital heart disease can be cannulated for CPB in a variety of ways. The ascending aorta is most commonly cannulated for arterial inflow with central cannulation. Central venous cannulation is most commonly via the superior and inferior vena cavae when intracardiac work is needed (bicaval cannulation), whereas a single right atrial cannula may be used when the heart does not

need to be opened and there are no communications between the left and right heart (single venous cannulation). Peripheral cannulation for smaller pediatric patients may be through the neck vessels, whereas larger patients are typically supported through groin cannulation. Figure 1.13 depicts a structurally normal heart to illustrate cannulation sites relative to the general cardiac anatomy and surrounding structures. Figure 1.14 depicts single arterial and bicaval venous cannulation with an aortic root needle and left ventricular vent also in place. Figures 1.15 and 1.16 illustrate normal left aortic arch and central venous anatomy for clinician reference.

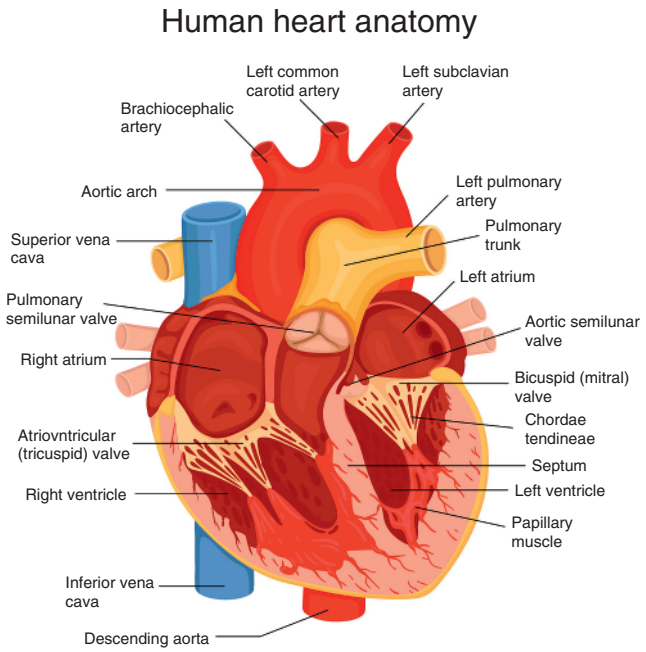


Figure 1.13 General anatomy of the heart and surrounding structures. https://en.wikipedia.org/wiki/File:Relations_of_the_aorta,_trachea,_esophagus_and_other_heart_structures.png. Wikipedia. Reproduced with permission under the Creative Commons Attribution-Share Alike 3.0 Unported license. Attribution: Mikael Häggström and ZooFari (accessed November 27, 2025). *Source:* Bulgakova Kristina / Adobe Stock Photos.

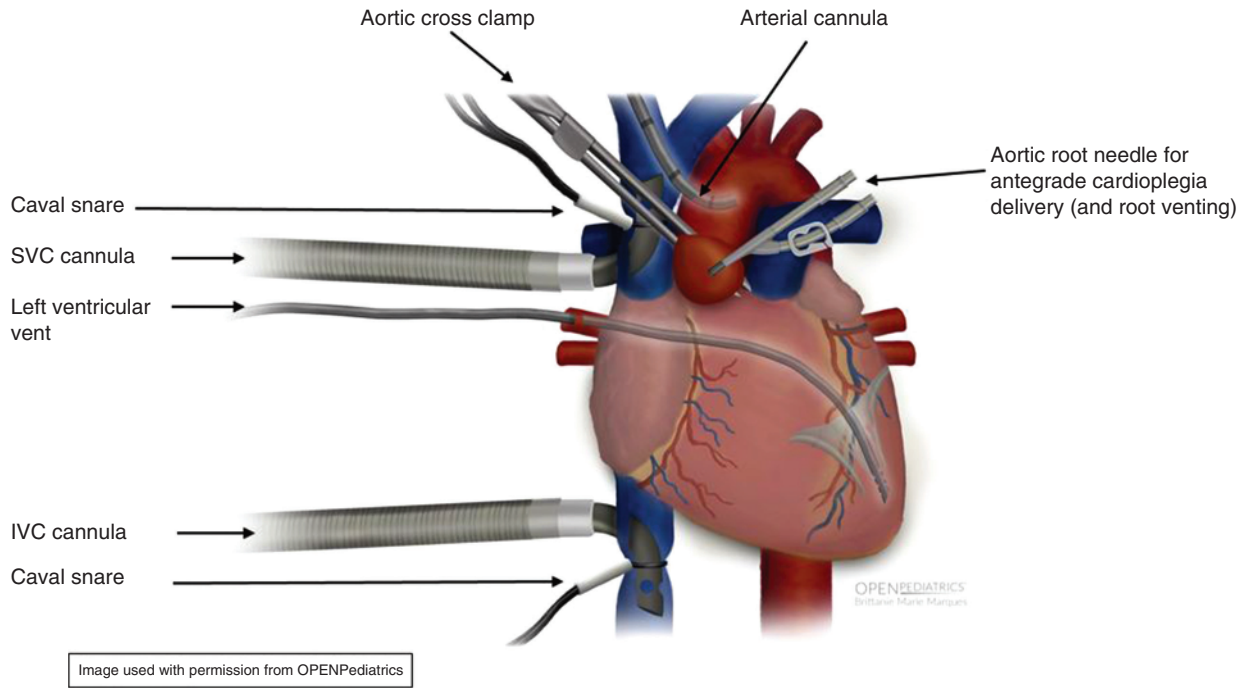


Figure 1.14 Common cannulation strategy for CPB. Adapted for use with permission from OpenPediatrics.

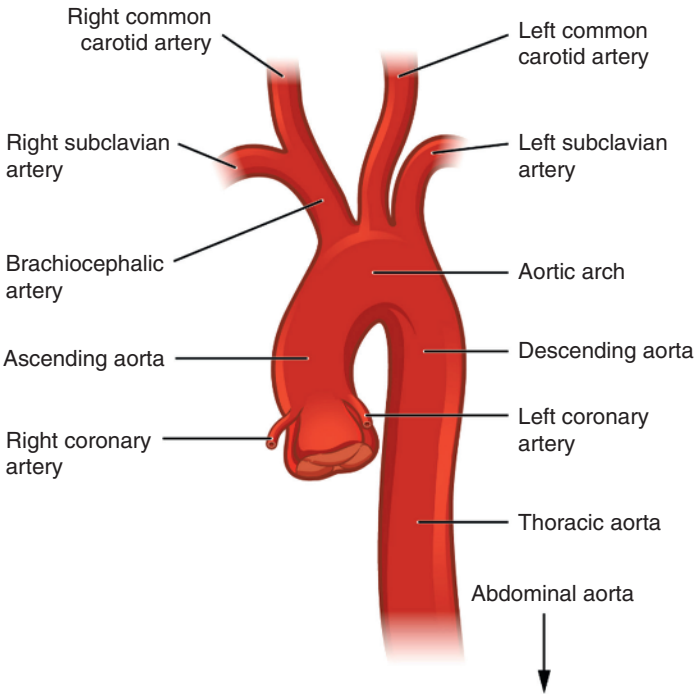


Figure 1.15 Aortic arch anatomy. OpenStax / https://anatomytool.org/content/openstax-anatphys-fig2025-aorta-english-labels / last accessed Mar. 20, 2026 / CC BY 4.0.

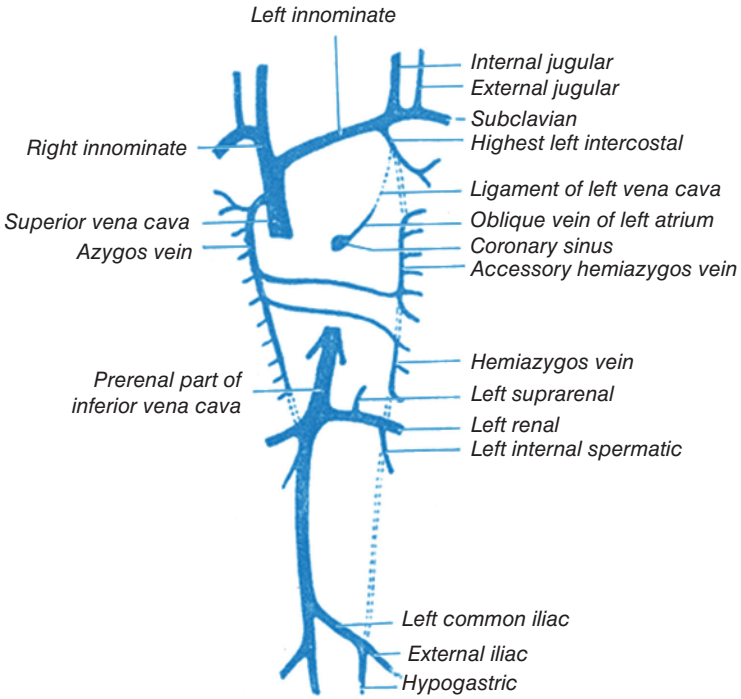


Figure 1.16 Central venous anatomy. From *Gray's Anatomy of the Human Body*, 1918 edition Henry Gray / https://commons.wikimedia.org/wiki/File:Gray480.png / Public domain.

Regarding cannulae, is it cannulae or cannulas? These terms are used interchangeably for the plural of cannula. The term "cannulas" is more common in conversation, whereas the term "cannulae" seems to be more common in written form.

There are literally hundreds of different cannulae available for CPB. The range of cannulae that need to be readily available for a congenital cardiac program is quite extensive to cover patients of all sizes, from 1 to 200 kg! In addition to the arterial and venous cannulae, a perfusion practice must have on hand aortic root needles of various sizes, retrograde coronary sinus and coronary perfusers, left ventricular vents, and of course connectors and tubing to incorporate these items into the bypass circuit. It is beyond the scope of this chapter to review all available cannulae. Rather, a review of commonly used arterial and venous cannulae is provided, as these are the essential cannulae which allow for traditional cardiopulmonary support.

It is an underappreciated fact that cannulae do not come from the manufacturer with specific rated flows, or recommended flows, as is the case with oxygenators and ALFs. Rather, cannulae come with charts depicting flow versus pressure drop (also called pressure loss). These charts are based on manufacturer-based measurements using water flow at room temperature and may therefore be referred to as "water charts." It is generally accepted that blood is 4–6 times more viscous than water, and this is an important consideration when analyzing cannulae pressure-loss versus flow charts. The manufacturer-provided charts do not factor in tubing length connecting the cannula to the bypass equipment, temperature changes during a case, patient-specific hematocrit, the use of augmented venous return, or several other factors that may impact the actual flow capability of a specific cannula. It is therefore imperative that a perfusion program develop their own experiential charts rating flow capabilities for cannulae within their CPB system. These experience-based charts are essential in a congenital cardiac surgery program where dozens of options exist due to considerable variation in patient and vessel size. Chapter 13 provides an example of consolidated experience-based equipment selection charts for a perfusion practice. The consolidated charts are useful for quick reference in terms of tubing pack selection along with primary cannulae options. Chapter 15 provides a wealth of water-chart data for arterial and venous cannulae in a separate section to serve as source material for a perfusion practice developing their own canulae inventory options and experience-based quick-reference charts.

A final note on cannulae options is that perfusion teams must stock a very large array of cannulae and not all options will be regularly utilized. Nonetheless, for patient safety, these low-usage-volume cannulae must be available. A perfusion team must have an established system for rotating stock to ensure products with the nearest expiration dates get utilized first. Further, there must be an established system for reviewing storage locations to ensure products are removed from the clinical space before their expiration date. See example *Stocking and Expiration Check Policy* in Chapter 17 for more details.

An overview of factors determining arterial and venous cannulae size is provided below.

Venous cannulae

Venous cannulae are qualified based on their French size (Fr). Most manufacturers use the outer diameter (OD) to determine French size. It is generally accepted that with gravity drainage through a venous cannula, the pressure drop across the cannula should be limited to 40 mmHg. A venous cannula with a larger internal lumen will obviously have a lower pressure drop and increased flow capacity. However, there are other important considerations. Venous cannulae are made with different materials and have variable tip designs usually consisting of additional side port holes. Different cannula designs, tip materials (metal, polycarbonate, plastic, silicone-based), and construction methods result in different ratios between the inner and outer diameter of the cannula. All of these differences may be important to the cannulating surgeon. Metal tips tend to have the benefit of maximized inner to outer (I/O) diameter ratios but are rigid. Silicone-based tips have less favorable (I/O) ratios as compared to metal tips but are less rigid and tend to be more conical, which may aid insertion, for example, into a cava. It is important to note that while venous cannulae are graded based on OD, flow capabilities will vary due to these factors.

It is also important to note that a larger venous cannula inserted into a cava does not always result in a higher expected flow rate. If the side port holes are occluded, venous return can be limited to a single hole at the tip, which may decrease overall performance. Furthermore, the IVC cannula must not occlude the hepatic venous drainage. The Eustachian valve is also of consideration for IVC cannulation since it can hinder proper cannula placement. Other factors impacting venous cannula performance, relative to water-chart data, include whether augmented venous return is used, the length of the venous

limb of the circuit, and the internal diameter of the venous limb. Ultimately, the patient's anatomy, anticipated flows on bypass, surgical needs, and surgeon's judgment determine venous cannulae size.

A flow probe on the venous limb of the circuit is an incredibly useful tool in assessing venous return, through one or more cannulae, in an objective fashion. For example, a surgeon may bicavally cannulate and then ask the perfusionist to assess venous flow with one caval cannula clamped. With a venous flow probe, the perfusionist can immediately see the venous flow rate and precisely match the arterial inflow to verify the flow assessment. This can be done for both cannula and the data can be used as needed if venous return is decreased later in the case. Furthermore, it is essential for the cardiac surgical team to have a protocol for addressing poor venous return on bypass. In terms of venous drainage issues relating to cannulae, it is worth noting that luminal obstruction of a venous cannula can occur during the CPB period (79, 80). This needs to be considered during troubleshooting.

A novel approach to venous cannulae design is the *Venous Smart Canula* (sic) manufactured by CLS Surgical (Liverpool, UK). A primary issue with venous cannula sizing is matching cannula OD to vessel wall inner diameter to maximize drainage, without injuring the vessel (81). The CLS Surgical line of venous cannulae approaches this issue with a flexible collapsed venous cannula that can be expanded in situ to the exact vessel size and then collapsed before removal. This is ideal for minimizing insertion size while maximizing flow capacity, as shown in Figure 1.17.

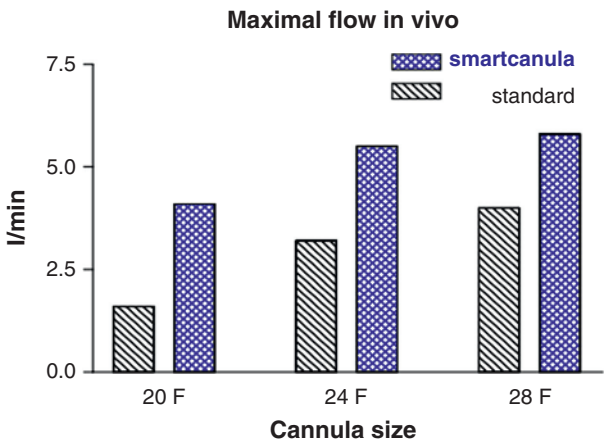


Figure 1.17 CLS Surgical Smart Venous Canula (sic) achievable flow comparison versus standard venous cannula. The gray boxes represent the flow rate of standard venous cannula of a given size. The blue boxes represent the achievable flow rate once the Smart Venous Canula is dilated to its maximal size. To note, the cannula is dilated up to the native vessel size per surgeon judgment. Image used with permission by CLS Surgical (Liverpool, UK).

The current line of *Venous Smart Canula* all have collapsed sizes less than 18Fr when placed over the insertion mandrel. This facilitates insertion. These cannulae can then be expanded up to maximum sizes of 36Fr or 45Fr. All current options include a 3/8″ barrel for connection to the CPB circuit with several length options based on insertion site requirements. Currently, the minimum insertion length for the smallest option is approximately 3.25″. To note, the CLS Surgical cannula line is not currently available in the United States.

Arterial cannulae

Arterial cannulae are also qualified based on their French size. As with venous cannulae, arterial cannulae French size refers to the OD. It is generally accepted that the pressure drop across an arterial cannula should be limited to 100 mmHg to prevent excessive jetting, shear forces, and damage to the formed elements of the blood. It is important that an arterial cannula is not so large that it blocks flow around it, which is particularly important for ascending aortic cannulation. Native cardiac output is ideally not significantly impacted by arterial cannulation, particularly during the initiation, rewarming, and weaning phases of bypass or when the patient is cannulated but not on CPB. Additionally, the length of the cannula with smallest diameter, and whether the cannula is compressible (likelihood to kink or be restricted by the purse strings), will impact performance. As with venous cannulae, functional performance is multifactorial (82).

Some arterial cannulae come with a barrel side port (i.e., luer port, vent port) allowing for stopcock placement. This is useful for monitoring central arterial pressure post bypass (on bypass, it only reflects bypass circuit pressure) and as a means for deairing during cannulation (prebypass and emergently).

See *Chapter 13, Consolidated Experience-based Equipment Selection Charts for Cardiopulmonary Bypass* and *Chapter 15, Arterial and Venous Cannulae Reference Data* for cannula-specific data, including an example of cannula selection based on patient body weight.

The perfusion record

The perfusion record is an essential component of the CPB set up. In fact, the 2025 AmSECT *Standards and Guidelines for Pediatric and Congenital Perfusion Practice* specify in Standards 4.1 and 4.2 that the perfusion record must be part of the patient's permanent medical record and it must include patient demographics, HLM data, blood gas

results, and anticoagulation results, along with a list of other items (15). The ideal perfusion record includes enough data to allow for a reconstruction of the CPB period and how the case progressed from start to finish. Ideally, monitored parameters automatically feed into the perfusion record on a minute-to-minute basis to allow for discrete review at a later time, as needed. This data should come from the HLM, vital sign monitor, and ancillary devices such as the near-infrared spectroscopy monitor. The perfusion record must also include free-text documentation as needed. Most importantly, the perfusionist is obligated to document (in real time or after CPB) outlier events and interventions which were aimed at addressing identified problems during CPB. As the perfusion record is an essential component of the patient's medical record, downtime procedures must be established in situations when the electronic capture of CPB and patient vital signs is interrupted.

The move toward electronic health records and electronic perfusion records has greatly increased the quality of data for retrospective analysis. This aids internal quality assurance case reviews as well as data entry into large-scale national and international registries. Importantly, the electronic perfusion record must be the Health Insurance Portability and Accountability Act (HIPAA) compliant and must follow safe practices for cybersecurity (83).

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