American Society of ExtraCorporeal Technology
Standards and Guidelines
for Pediatric and Congenital Perfusion Practice

The American Society of ExtraCorporeal Technology (AmSECT) has created the following document based on clinical evidence and currently accepted perfusion practices. Perfusionists are the only allied healthcare professionals formally trained and educated in the field of extracorporeal science and whose scope of practice expressly includes the utilization of extracorporeal devices The document is intended to serve as a useful guide for teams developing institution-specific protocols to improve the reliability, safety and effectiveness of extracorporeal support services.

Goal Statement
The goal of this project was to provide Perfusionists with a framework to guide safe and effective extracorporeal support care to their patients. AmSECT recommends that clinical teams use this document as a guide for developing institution-specific protocols for patients receiving extracorporeal support.

To facilitate the understanding of the Standards and Guidelines, we define important terms used through the document.

Definitions:
Standard: Practices, technology and/or conduct of care that institutions shall meet in order to fulfill the minimum requirements for cardiopulmonary bypass.

***Guideline*:** A recommendation that should be considered and may assist in the development and implementation of protocols.

Protocol: An institution-specific written document, derived from professional standards and guidelines, which contains decision and treatment algorithms.

Word Usage:

Shall: In this document, the word <u>shall</u> is used to indicate a mandatory requirement.

Should: In this document, the word <u>should</u> is used to indicate a recommendation.

Surgical Care Team: In this document, the term surgical care team is used to indicate the group surgeon, anesthesiologist, Perfusionist, nurse and technicians.

Important Note on Scope:
AmSECT recognizes that individual medical centers may have local policies that may supersede AmSECT's Standards and Guidelines. Likewise, AmSECT recognizes that some districts or states may have laws that supersede AmSECT's Standards and Guidelines. As a result, Perfusionists practicing within those jurisdictions should comply in all respects with those policies and laws. These Standards and Guidelines may also be superseded by the judgment of the healthcare professional taking into account the facts and circumstances of the individual case.

American Society of ExtraCorporeal Technology

Standards and Guidelines
For Pediatric and Congenital
Perfusion Practice

Accepted May 2019

Standard 1:	**Development of Institutionally-based Protocols**
Standard 2:	**Qualification, Competency and Support Staff**
Standard 3:	**Communication**
Standard 4:	**Perfusion Record**
Standard 5:	**Checklist**
Standard 6:	**Safety Devices**
Standard 7:	**Monitoring**
Standard 8:	**Anticoagulation**
Standard 9:	**Gas Exchange**
Standard 10:	**Blood Flow**
Standard 11:	**Blood Pressure**
Standard 12:	**Circuitry**
Standard 13:	**Priming**
Standard 14:	**Protamine and Cardiotomy Suction**
Standard 15:	**Blood Management**
Standard 16:	**Fluid Management**
Standard 17:	**Level of Readiness**
Standard 18:	**Staffing**
Standard 19:	**Duty Hours**
Standard 20:	**Quality Assurance and Improvement**
Standard 21:	**Maintenance**

<u>Standard 1: Development of Institutionally-based Protocols</u>

Standard 1.1: As a mechanism for applying each standard to clinical practice, an institution or service provider shall develop and implement an operating procedure (protocol) for each of the standards.

Standard 1.2: The protocol shall be:

- Approved by the Chairman of Cardiac Surgery, or his/her designee, Director of Perfusion or equivalent, and other relevant clinical governance committees if available.
- Reviewed and revised annually or more frequently when deemed necessary.

Guideline 1.1: Deviation from protocol may be at the discretion of the Surgical Care Team and should be documented in the perfusion record.

Standard 2: Qualification, Competency and Support Staff

Standard 2.1: A Perfusionist, who is Board Certified by the American Board of Cardiovascular Perfusion or who demonstrates equivalent qualifications and competency, shall conduct cardiopulmonary bypass (CPB).[1]

Standard 2.2: Perfusionist competency shall be assessed annually to evaluate compliance with departmental protocols.

Standard 2:3: The Perfusionist shall attend, participate, and engage in perfusion-related continuing education courses on an annual basis.[2]

Standard 2.4: Support staff shall be available on site to assist the primary Perfusionist during CPB procedures

Standard 2.5: A process to educate, train, and annually evaluate perfusion staff shall be developed and followed.

Guideline 2.1: An individual graduating from an accredited perfusion education program should complete all requirements for American Board of Cardiovascular Perfusion certification within 3 years of graduation.

Guideline 2.2: A standardized process should be developed and followed to identify, orient and educate support staff to ensure they have general knowledge of the duties performed by the Perfusionist, flow of the operation and location of primary and ancillary items required during CPB. Support staff may include a Perfusionist, nursing, technical, or non- technical staff.

Guideline 2.3: American Board of Cardiovascular Perfusion continuing education units (CEUs) should be obtained from pediatric content whenever possible.

[1] AmSECT recognizes that individual states may license Perfusionists based on other criteria. These laws supersede this standard.

[2] American Board of Cardiovascular Perfusion, *www.abcp.org/* (accessed November 30, 2016)

Standard 3: Communication

Standard 3.1: A patient-specific management plan for the cardiopulmonary bypass (CPB) procedure shall be prepared and communicated to the surgical team either during the pre- operative briefing or prior to beginning the procedure.[3]

Standard 3.2: The primary Perfusionist shall use a set handoff protocol e.g. SBAR when transitioning the management of the case to a second Perfusionist.[4]

Guideline 3.1: The use of cellular telephone technology in the operating room should be guided by the principles of ST-59 Statement on use of cell phones in the operating room, written by the American College of Surgeons.[5]

Guideline 3.2: Protocol driven communication (e.g. closed-loop), should be utilized to acknowledge verbal commands, verify the content, and reduce ambiguity.[6, 7, 8]

Guideline 3.3: The primary Perfusionist should participate in the post-procedure debrief with the surgical team.

---

[3] World Health Organization surgical safety checklist and implementation manual. World Health Organization, http://www.who.int/patientsafety/safesurgery/ss_checklist/en/ (accessed November 30, 2016)

[4] The Joint Commission. Hot Topics in Health Care. Transitions of Care: The need for a more effective approach to continuing patient care. http://www.jointcommission.org/assets/1/18/hot_topics_transitions_of_care.pdf (accessed 14th October 2016)

[5] Statement on use of cell phones in the operating room, September 2008, Volume 93, Number 9. Bulletin of the American College of Surgeons, https://www.facs.org/~/media/files/publications/bulletin/2008/2008%20september%20bulletin.ashx (accessed November 30, 2016)

[6] Wadhera RK, Parker SH, Burkhart HM, Greason KL, Neal JR, Levenick KM, Wiegmann DA, Sundt TM, 3rd. Is the "sterile cockpit" concept applicable to cardiovascular surgery critical intervals or critical events? The impact of protocol-driven communication during cardiopulmonary bypass. *J Thorac Cardiovasc Surg*. 2010;139:312-319

[7] Whyte S, Cartmill C, Gardezi F, Reznick R, Orser BA, Doran D, Lingard L. Uptake of a team briefing in the operating theatre: A burkean dramatistic analysis. *Soc Sci Med*. 2009;69:1757-1766

[8] de Vries EN, Prins HA, Crolla RM, den Outer AJ, van Andel G, van Helden SH, Schlack WS, van Putten MA, Gouma DJ, Dijkgraaf MG, Smorenburg SM, Boermeester MA. Effect of a comprehensive surgical safety system on patient outcomes. *N Engl J Med*. 2010;363:1928-1937

Standard 4: Perfusion Record

Standard 4:1: The perfusion record (written and/or electronic) for each cardiopulmonary bypass (CPB) procedure shall be included as part of the patient's permanent medical record. The perfusion records shall be maintained and stored according to institution policy for retaining patient medical records.

Standard 4.2: The record shall include:

- Patient information including demographics and pre-operative risk factors (Appendix A).
- Information sufficient to accurately describe the procedure, personnel, and equipment (Appendix B).
- Patient physiological parameters documented at a frequency determined by institutional protocol (Appendix C).
- Blood gas and anticoagulation monitoring results (Appendix D).
- Signature of the Perfusionist (and all relief Perfusionists) performing the procedure.

Guideline 4.1: The perfusion record should include open text (factual) commentary including supervising physician verbal orders pertinent to the CPB procedure.

Guideline 4.2: The perfusion record should include the signatures of the physician(s) providing oversight for the CPB procedure.

Guideline 4.3: Raw data (e.g. blood flow, pressure and temperature values) contained in electronic perfusion databases should be stored for a time period in accordance with your institution's policy for retaining electronic patient medical records.

Standard 5: Checklist

Standard 5.1: The Perfusionist shall use a checklist for each cardiopulmonary bypass (CPB) procedure.[9]

Standard 5.2: Checklists shall be included as part of the patient's permanent medical record.

Guideline 5.1: The Perfusionist should use checklists in a read-verify manner where critical steps that should have been performed are confirmed.[10] Completion of the checklist should be performed by two people, one person being the primary Perfusionist responsible for operation of the heart lung machine during the intra-operative period.

Guideline 5.2: The Perfusionist should utilize a checklist throughout the entire peri-operative period (e.g. set-up, pre-bypass, initial onset of bypass, prior to cessation of bypass, post bypass, and/or any return to bypass).

Guideline 5.3: The Perfusionist should utilize a checklist for other ancillary perfusion services (e.g. cell salvage, intra-aortic balloon pump, extracorporeal membrane oxygenation).

[9] Haynes AB, Weiser TG, Berry WR, Lipsitz SR, Breizat AH, Dellinger EP, Herbosa T, Joseph S, Kibatala PL, Lapitan MC, Merry AF, Moorthy K, Reznick RK, Taylor B, Gawande AA; Safe Surgery Saves Lives Study Group. A surgical safety checklist to reduce morbidity and mortality in a global population. N Engl J Med. 2009 29;360(5):491-9.
[10] Advancing Patient Safety in the U.S. Department of Veterans Affairs. Preoperative Briefing Guide for Use in the Operating Room. Commonwealth Fund Pub. 1477, Vol 9.

Standard 6: Safety Devices

Standard 6.1: Pressure monitoring of the arterial line, cardioplegia delivery systems and venous reservoir (when augmented venous drainage is utilized), shall be employed during cardiopulmonary bypass (CPB) procedures.

- The pressure monitor shall be either servo regulated to control the arterial/cardioplegia pump or to allow interruption to the arterial/cardioplegia flow.
- The pressure monitor shall include an audible and visual alarm.

Standard 6.2: A bubble detector shall be employed during CPB procedures

- The gross/macro bubble detector shall be used to control the arterial pump or to allow interruption of the arterial blood flow.
- The detector system shall include an audible and visual alarm, and be positioned according to manufacturer instructions for use to enable timely identification and action.

Standard 6.3: A level sensor shall be employed during CPB procedures utilizing a (hard- shell) reservoir.

- The level sensor shall be either servo regulated to control the arterial pump or to allow interruption of the arterial blood flow.
- The level sensor shall include an audible and visual alarm, and be positioned according to manufacturer's instructions to allow an appropriate reaction time and a safe operational volume.

Standard 6.4: Temperature monitoring of the arterial outflow from the oxygenator shall be employed during CPB procedures.

- The temperature sensor shall include an audible and visual alarm to prevent high arterial outlet temperatures.

Standard 6.5: An arterial-line filter shall be employed during CPB procedures.

Standard 6.6: A one-way valve in the vent line shall be employed during CPB procedures.

Standard 6.7: A method for retrograde flow avoidance when using a centrifugal pump shall be employed during CPB procedures.

- Examples of retrograde avoidance systems may include the following:
  - One way flow valves
  - Hard stop detent controls to prevent accidental reduction in pump speed
  - Electronically activated arterial line clamps
  - Low speed visual and audible alarm.

Standard 6.8: An anesthetic gas scavenge line shall be employed whenever inhalation agents are introduced into the circuit during CPB procedures.

Standard 6.9: Hand cranks shall be readily available during CPB procedures.

Standard 6.10: A back-up gas supply shall be available during CPB procedures.

Standard 6.11: A back-up battery supply for the CPB machine shall be available during CPB procedures.

Guideline 6.1: A ventilating gas oxygen analyzer should be employed during CPB procedures.

Guideline 6.2: A level sensor should be employed during CPB procedures utilizing a soft shell reservoir.

- The level sensor should be either servo regulated to control the arterial pump or to allow interruption of the arterial blood flow.
- The level sensor should include an audible and visual alarm, and be positioned according to manufacturer's instructions to allow an appropriate reaction time and a safe operational volume.
- The use of an air bubble detector distal to the outlet can be used utilized as a surrogate level detector.

Guideline 6.3: The gross/macro bubble detector should be used to control the cardioplegia pump to allow interruption of the cardioplegia and/or modified ultrafiltration (MUF) blood flow.

Standard 7: Monitoring[11]

Standard 7.1: Patient arterial blood pressure shall be monitored continually during cardiopulmonary bypass (CPB).

Standard 7.2: Arterial line pressure shall be monitored continually during CPB.

Standard 7.3: Arterial blood flow shall be monitored continually during CPB.

Standard 7.4: Cardioplegia dose, delivery method, line pressure (antegrade), coronary sinus pressure (retrograde) and ischemic intervals shall be monitored continually during CPB.

Standard 7.5: Patient and device temperatures shall be monitored continually during CPB.

- Patient (e.g. nasopharyngeal, rectal, bladder, esophageal)
- Heart lung machine (arterial, venous and cardioplegia)
- Heater cooler (H_20 temperature)

Standard 7.6: Blood gas analysis shall be monitored continually or at regular intervals during CPB (Appendix D).

Standard 7.7: Continuous blood gas monitoring shall be used during CPB.[12, 13]

Standard 7.8 Hematocrit (or hemoglobin) shall be monitored continually during CPB.

Standard 7.9: Oxygen fraction and gas flow rates shall be monitored continually during CPB (Appendix D).

Standard 7.10: The percentage of venous line occlusion of the venous occluder shall be monitored continually during CPB.

Standard 7.11: Venous oxygen saturation shall be monitored continually during CPB.

---

[11] To be performed in conjunction with Standard 3.

[12] Ottens J, Tuble SC, Sanderson AJ, Knight JL, Baker RA. Improving cardiopulmonary bypass: Does continuous blood gas monitoring have a role to play? The journal of extra-corporeal technology. 2010;42(3):191.

[13] Trowbridge CC, Vasquez M, Stammers AH, et al. The effects of continuous blood gas monitoring during cardiopulmonary bypass: A prospective, randomized study--part II. The journal of extra-corporeal technology. 2000;32(3):129.

Standard 7.12: Cerebral oximetry shall be monitored during CPB.[14, 15, 16, 17]

Standard 7.13: Arterial blood flow shall be monitored continually at a point in the CPB circuit where it accurately reflects the flow delivered to the patient during CPB (eg distal to intra- circuit shunts).[18, 19]

Guideline 7.1: Carbon dioxide removal should be monitored continually during CPB.

Guideline 7.2: Arterial oxygen saturation should be monitored continually during CPB.

Guideline 7.3**:** The following patient pressures should be monitored during CPB

- Central venous pressure

Guideline 7.4: Somatic oximetry should be monitored continually during CPB.[20, 21, 22, 23]

---

[14] Hoffman, George M., Ghanayem, Nancy S., Scott, John P., Tweddell, James S., Mitchell, Michael E., Mussatto, Kathleen A.. Postoperative cerebral and somatic near-infrared spectroscopy saturations and outcome in hypoplastic left heart syndrome. Annals of Thoracic Surgery. 2016;103(5):1527-1535.

[15] Redlin M, Koster A, Huebler M, et al. Regional differences in tissue oxygenation during cardiopulmonary bypass for correction of congenital heart disease in neonates and small infants: Relevance of near-infrared spectroscopy. The Journal of Thoracic and Cardiovascular Surgery. 2008;136(4):962-967.

[16] Redlin M et al. Detection of lower torso ischemia by NIRS during CPB in a 6.8kg infant with complex aortic anatomy. Ann Thorac Surg. 2006;82:323-5.

[17] Fenton KN et al. The significance of baseline cerebral oxygen saturation in children undergoing congenital heart surgery. Am J surg. 2005;190:260-3.

[18] Lee-Sensiba K, et al. Errors in Flow and Pressure related to the arterial filter purge line. JECT 1998; 30(2):77-82.

[19] Wang S, Miller A, Myers J, Undar A. "Stolen" Blood Flow: Effect of an Open Arterial Filter Purge Line in a Simulated Neonatal CPB Model. ASAIO 2008; 54:432-435.

[20] Booth EA, Dukatz C, Ausman J, Wider M. Cerebral and somatic venous oximetry in adults and infants. Surgical neurology international. 2010;1(1):75.

[21] R. M. Cerbo, R. Cabano, A. Di Comite, S. Longo, R. Maragliano & M. Stronati (2012) Cerebral and somatic rSO2 in sick preterm infants, The Journal of Maternal-Fetal & Neonatal Medicine, 25:sup4, 89-92.

[22] Hoffman, G, Ghanayem, NS, Scott, JP, Tweddell, JS, Mitchell, ME, Mussatto, KA. Postoperative cerebral and somatic near-infrared spectroscopy saturations and outcome in hypoplastic left heart syndrome. Annals of Thoracic Surgery. 2016;103(5):1527-1535.

[23] Thomassen SA, Kjærgaard B, Sørensen P, Andreasen JJ, Larsson A, Rasmussen BS. Regional muscle tissue saturation is an indicator of global inadequate circulation during cardiopulmonary bypass: A randomized porcine study using muscle, intestinal and brain tissue metabolomics. Perfusion. 2017;32(3):192-199.

Standard 8: Anticoagulation

Standard 8.1: The Perfusionist, in collaboration with the physician-in-charge, shall define the intended treatment algorithm for anticoagulation management (heparin) and an alternative algorithm for when heparin is not suitable, including acceptable ranges for ACT.

Standard 8.2: The Perfusionist shall work closely with the surgical care team to monitor and treat the patient's anticoagulation status before, during, and after the cardiopulmonary bypass (CPB) period.

Guideline 8.1: The surgical care team should determine the target activated clotting time by considering relevant factors; including variability in the measurement of activated clotting time (ACT) attributed to the device's performance characteristics.

Guideline 8.2: Patient-specific initial heparin dose should be determined by one of the following methods:

- Weight
- Dose Response Curve (automated or manual)
- Blood Volume
- Body Surface Area

Guideline 8.3: Anticoagulation monitoring should include the testing of ACT. Additional monitoring tests may include:

- Heparin level measurement (e.g. heparin/protamine titration or unfractionated heparin level)
- Partial Thromboplastin Time
- Thromboelastograph
- Thrombin Time
- Anti Xa

Guideline 8.4: A process should exist for identifying and managing heparin resistance.

Guideline 8.5: Additional doses of heparin during CPB should be determined by using an ACT and/or Heparin/Protamine titration.[24]

Guideline 8.6: Heparin reversal should be confirmed by ACT and/or heparin/protamine titration.

[24] In patients requiring longer CPB times (>2 to 3 hours), maintenance of higher and/or patient- specific heparin concentrations during CPB may be considered to reduce hemostatic system activation, reduce consumption of platelets and coagulation proteins, and to reduce blood transfusion. (Class IIb, Level of evidence B). Ferraris et al 2011

Standard 9: Gas Exchange

Standard 9.1: Gas exchange shall be maintained during cardiopulmonary bypass (CPB) according to protocol, accounting for:

- The individual patient characteristics/risk profile
- Oxygenator type, design and instructions for use.
- Blood flow, temperature, metabolic demand, and cerebral oximetry.

Standard 9.2: Devices used to measure gas exchange shall be calibrated according to the manufacturer's instructions for use.

Standard 9.3: Blood gas analysis shall be performed and recorded according to protocol.

Standard 9.4: The use of supplemental CO_2 and a microregulator shall be available to optimize blood gas management.[25, 26]

Guideline 9.1: Point-of-Care testing should be considered to provide accurate and timely information for blood gas analysis.[27]

Guideline 9.2: Oxygen delivery and consumption calculations should be utilized to evaluate and optimize gas exchange.[28]

- Oxygen Delivery: $DO_2 = 10 \times CI \times CaO_2$
- Oxygen Consumption: $VO_2 = 10 \times CI \times (CaO_2 - CvO_2)$

Where:

CaO_2 (arterial oxygen content) = $(Hb \times 1.36 \times SaO_2) + (0.0031 \times PaO_2)$, and

CvO_2 (mixed venous oxygen content) = $(Hb \times 1.36 \times SvO_2) + (0.0031 \times PvO_2)$

CI = cardiac index

HB = hemoglobin

SaO_2 = arterial oxygen saturation

PaO_2 = partial pressure of oxygen in arterial blood

SvO_2 = venous oxygen saturation

PvO_2 = partial pressure of oxygen in venous blood

---

[25] Pappa A, Shankaran S, Laptook AR, et al. Hypocarbia and Adverse Outcome in Neonatal Hypoxic-Ischemic Encephalopathy. J Pediatr. 2011;158(5):752-758.

[26] Quarti A, Nardone S, Manfrini F, et al. Effect of the adjunct of carbon dioxide during cardiopulmonary bypass on cerebral oxygenation. Perfusion. 2013;28(2):152-155.

[27] Nichols, JH. Laboratory Medicine Practice Guidelines. Evidence-based practice for point-of-care testing. American Association for Clinical Chemistry Press. 2006. https://www.aacc.org/~/media/practice-guidelines/point-of-care-testing/poct-entire-lmpg.pdf?la=en (accessed November 30, 2016)

[28] De Somer F, Mulholland JW, Bryan MR, Aloisio T, Van Nooten GJ, Ranucci M. O_2 and CO_2 production during cardiopulmonary bypass as determinants of acute kidney injury: time for a goal-directed perfusion management? Crit Care. 2011 Aug 10;15(4):R192. doi: 10.1186/cc10349.

Standard 10: Blood Flow

Standard 10.1: Target blood flow rates shall be determined prior to cardiopulmonary bypass (CPB) according to protocol.[16]

Standard 10.2: Blood flow rates shall be calculated utilizing one of the following methods:

- $L/min/m^2$
- L/kg/min

Standard 10.3: The Perfusionist shall work closely with the surgical care team to maintain targeted blood flow rate during CPB.

Standard 10.4: Aortic root vent flow shall be monitored and CPB flow shall be adjusted to accommodate for shunting so that total blood flow to the patient is not compromised.

Guideline 10.1: Variance from intended and targeted blood flow should be communicated to the physician-in-charge.

Guideline 10.2: Appropriate blood flow rate should be determined by evaluation of:

- Acid base balance
- Base Excess
- Anesthetic level
- Arterial blood pressure
- Cerebral oximetry
- Lactate burden
- Oxygen delivery and consumption (refer to guideline 10.2 for formula)
  - Venous pO_2
  - Arterial pO_2
  - Hemoglobin concentration
  - Arterial oxygen saturation
- Systemic vascular resistance (SVR)
- Temperature
- Venous oxygen saturation

Standard 11: Blood Pressure

Standard 11.1: The Perfusionist, in collaboration with the physician-in-charge, shall define and communicate the intended treatment algorithm for blood pressure management prior to cardiopulmonary bypass (CPB), including acceptable ranges for blood pressure based on age or weight.[29]

Standard 11.2: The Perfusionist shall work closely with the surgical care team to maintain blood pressure according to protocol during CPB.

Guideline 11.1: Variance from intended and targeted blood pressure should be documented and communicated to the physician-in-charge to allow for changes in the blood pressure management plan.

[29] In many circumstances, the physician-in-charge may direct the perfusionist to modify the intended blood pressure management to address circumstances occurring during the CPB procedure.

Standard 12. Circuitry

Standard 12.1: The Perfusionist shall select circuit components taking into consideration prime volume, surface area, safety, and the expected metabolic requirements of the patient.

Standard 12.2: Both the number and size of shunts within the circuit shall be minimized to prevent steal from arterial blood flow.[30, 31, 32]

Guideline 12.1: The Perfusionist should consider assisted venous return taking into consideration any patient specific contraindications.[33, 34, 35, 36]

---

[30] CPB Principles & Practice (3rd Ed) Chp #7: Splanchnic Visceral, Metabolic and Glucoregulatory Effects of CPB. G. Gravlee, R. Davis, A. Stammers, R. Ungerleider

[31] Lee-Sensiba K, et al. Errors in Flow and Pressure related to the arterial filter purge line. JECT 1998; 30(2):77-82.

[32] Wang S, Miller A, Myers J, Undar A. "Stolen" Blood Flow: Effect of an Open Arterial Filter Purge Line in a Simulated Neonatal CPB Model. ASAIO 2008; 54:432-435.

[33] Antunes N. et al. Vacuum assisted drainage in cardiopulmonary bypass: advantages and disadvantages. Rev Bras Cir Cardiovasc 2014;29(2):266-71.

[34] Durandy Y. Vacuum-Assisted Venous Drainage, Angel or Demon: PRO. JECT 2013;45:122-127.

[35] Durandy Y. The impact of VAVD and miniaturized bypass circuits on blood transdfusion in pediatric cardiac surgery. ASAIO J 2009;55:117-120

[36] Nakanishi K, et al. Usefulness of vacuum-assisted cardiopulmonary bypass circuit for pediatric open-heart surgery in reducing homologous blood transfusion. Eur J Cardiothorac Surg 2001; 20:233-238.

Standard 13. Priming

Standard 13.1: The Perfusionist shall consider the impact the prime has on the smaller circulating blood volume of the pediatric patient and its effect on:

- electrolyte levels
- colloid osmotic pressure
- coagulation

Standard 13.2: When priming with exogenous blood, a circuit prime gas and electrolyte levels shall be obtained prior to initiation of bypass and adjustments made to correct any physiologic abnormalities.[37, 38]

Guideline 13.1: When priming with exogenous blood, the use of prebypass ultrafiltration (preBUF) or washed red blood cells should be used during priming procedure.[39, 40, 41, 42, 43, 44]

Guideline 13.2: The perfusionist should consider matching prime composition to the individual patient values.

[37] Malmqvist G, Claesson Lingehall H, Appelblad M, Svenmarker S. Cardiopulmonary bypass prime composition: Beyond crystalloids versus colloids. Perfusion. 2018;1-6.
[38] F J Liskaser, R Bellomo, M Hayhoe, et al. Role of pump prime in the etiology and pathogenesis of cardiopulmonary bypass-associated acidosis. Anesthesiology. 2000;93(5):1170-1173.
[39] Boks RH, Golab HD, Takkenberg JJM, & Bogers JJC. Washing of irradiated red blood cells in pediatric cardiopulmonary bypass: is it clinically useful? A retrospective audit. European Journal of Cardiothoracic Surgery. 2012;41:283-286.
[40] Cholette JM, Henrichs KF, Alfieris GM, et al. Washing red blood cells and platelets transfused in cardiac surgery reduces postoperative inflammation and number of transfusions: Results of a prospective, randomized, controlled clinical trial. Pediatric Critical Care Medicine. 2012;13(3):290-299.
[41] O'Leary MF, Szklarski P, Klein TM & Young PP. Hemolysis of red blood cells after cell washing with different automated technologies: clinical implications in a neonatal cardiac surgery population. Transfusion Practice. 2011;51:955-960.
[42] Sasaki J, Tirotta C, Lim H, et al. Comparison of stored red blood cell washing techniques for priming extracorporeal circuits. Perfusion. 2018;33(2): 130-135.
[43] Shimpo H, Shimamoto A, Miyake Y, et al. Effect of ultrafiltration on priming solution with preserved blood for extracorporeal circulation in infants. ASAIO J. 1996;42:M792–4.
[44] Swindell CG, Barker TA, McGuirk SP, et al. Washing of irradiated red blood cells prevents hyperkalemia during cardiopulmonary bypass in neonates and infants undergoing surgery for complex congenital heart disease. European Journal of Cardiothoracic Surgery. 2007;31;659-664.

Standard 14. Protamine and Cardiotomy Suction.

Standard 14.1: Cardiotomy suction shall be discontinued at the onset of protamine administration to avoid clotting within the CPB circuit.

Standard 15: Blood Management

Standard 15.1: The Perfusionist shall participate in efforts to minimize hemodilution and avoid unnecessary blood transfusions.[45]

Standard 15.2: The Perfusionist shall minimize the cardiopulmonary bypass (CPB) circuit size to reduce prime volume.[46] See Standard 12. Circuitry

Standard 15.3: The Perfusionist shall calculate and communicate to the surgical team prior to initiating CPB, a patient's predicted post-dilutional hemoglobin or hematocrit.

Standard 15.4: Minimum acceptable hematocrit during and prior to termination of cardiopulmonary bypass (CPB) shall be maintained according to institutional protocol.

Guideline 15.1**:** Blood management efforts should include the following [46, 46, 47, 48, 49, 50, 51]:

- Participation in a multidisciplinary blood management team.
- Minimize hemodilution by:
    - Matching the size of the CPB circuit to the size of the patient. See Standard 12: Circuitry.
    - Autologous priming of CPB circuit, including retrograde arterial and venous antegrade priming
- Biocompatible coating on the surface of all CPB components
- Perioperative blood cell recovery and reinfusion after being appropriately processed.
- CPB circuit blood salvage at the end of the procedure
- Preoperative whole blood removal: Acute Normovolemic Hemodilution (ANH)

Guideline 15.2: Point-of-Care hemostasis monitoring should be utilized to minimize blood loss. Monitoring may include:

- International normalized ratio
- Partial thromboplastin time
- Thrombin time

---

[45] Ferraris VA, et al. 2011 update to the Society of Thoracic Surgeons and the Society of Cardiovascular Anesthesiologists blood conservation clinical practice guidelines. *Ann Thorac Surg* 2011 Mar;91(3):944-82.
[46] Crescini WM, Muralidaran A, Shen I, et al. The use of acute normovolemic hemodilution in pediatric cardiac surgery. Acta Anaesthesiologica Scandinavica. 2018;62:756-764.
[47] Freisen RH, Perryman KM, Weigers KR, et al. A trial of fresh autologous whole blood to treat dilutional coagulopathy following cardiopulmonary bypass in infants. Pediatric Anesthesia. 2006;16(4):429-435.
[48] Hodge A, Cohen A, Winch P, Tumin D, Burnside J, Ratliff T, Galantowicz M, Naguib A. The Effect of Autologous Blood Priming on Cerebral Oximetry in Congenital Cardiac Surgery Patients. J Extra Corpor Technol 2017;49:168-173.
[49] Naguib, Aymen N., et al. "A Single-center Strategy to Minimize Blood Transfusion In neonates and Children Undergoing Cardiac Surgery." Pediatric Anesthesia 25.5 (2015): 477-86.
[50] Sebastian R, Ratliff T, Winch PD, et al. Revisiting acute normovolemic hemodilution and blood transfusion during pediatric cardiac surgery: a prospective observational study. Pediatric Anesthesia. 2016;27:85-90.
[51] Winch P, Naguib A, Bradshaw J, Galantowicz M, Tobias J. Decreasing the need for transfusion: Infant cardiac surgery using hemodilution and recombinant factor VIIa. Pediatr Cardiol. 2013;34(1):119-124.

- Thromboelastography/Thromboelastometry
- Platelet count
- Platelet function analysis

Guideline 15.3: The surgical team should consider the age of transfused blood.[52, 53, 54, 55]

Guideline 15.4: Efforts should be made to reduce the total number of donor exposures and utilize components from the same donor whenever possible.

[52] Cholette JM, Pietropaoli AP, Henrichs KF, et al. Longer RBC storage duration is associated with increased postoperative infections in pediatric cardiac surgery. Pediatric critical care medicine : a journal of the Society of Critical Care Medicine and the World Federation of Pediatric Intensive and Critical Care Societies. 2015;16(3):227-235.
[53] Manlhiot C, McCrindle, Brian W, Menjak, IB, Yoon, H, Holtby, HM, Brandão, LR, et al. Longer blood storage is associated with suboptimal outcomes in high-risk pediatric cardiac surgery. Annals of Thoracic Surgery. 2012;93(5):1563-1569.
[54] Ranucci M, Carlucci C, Isgrò G, et al. Duration of red blood cell storage and outcomes in pediatric cardiac surgery: An association found for pump prime blood. Critical care (London, England). 2009;13(6):R207.
[55] Redlin M, Habazettl H, Schoenfeld H, et al. Red blood cell storage duration is associated with various clinical outcomes in pediatric cardiac surgery. Transfusion Medicine and Hemotherapy. 2014;41(2):146-151.

Standard 16: Fluid Management

Standard 16.1: Fluid balance shall be monitored continually and documented during cardiopulmonary bypass (CPB).[56, 57, 58, 59]

Guideline 16.1: The use of modified ultrafiltration (MUF) should be utilized (unless contraindicated) to optimize hemodynamics and hematocrit.[60, 61, 62, 63]

Guideline 16.2: The use of dilutional or zero balance ultrafiltration (ZBUF) should be considered during CPB.[64, 65, 66, 67, 68, 69, 70]

---

[56] Grist G, Whittaker C, Merrigan K, et al. The Correlation of Fluid Balance Changes During Cardiopulmonary Bypass to Mortality in Pediatric and Congenital Heart Surgery Patients. The Journal of Extra-corporeal Technology. 2011;43(4):215-226.
[57] Toraman F, Evrenkaya S, Yuce M, et al. Highly positive intraoperative fluid balance during cardiac surgery is associated with adverse outcome. Perfusion. 2004;19:85-91.
[58] Lex DJ, Tóth R, Czobor NR, et al. Fluid Overload Is Associated With Higher Mortality and Morbidity in Pediatric Patients Undergoing Cardiac Surgery. Pediatr Crit Care Med. 2016 Apr;17(4):307-14.
[59] Casteneda A et al. Cardiac surgery of neonate and infant: Chapter 2 Cardiopulmonary Bypass, hypothermia, and circulatory arrest. In: Morbidity of cardiopulmonary bypass, 1st Ed. Philadelphia: WB Saunders Company, 1994:25
[60] Ricci Z, Polito A, Netto R, et al. Assessment of modified ultrafiltration hemodynamic impact by pressure recording analytical method during pediatric cardiac surgery. Pediatric critical care medicine : a journal of the Society of Critical Care Medicine and the World Federation of Pediatric Intensive and Critical Care Societies. 2013;14(4):390-395.
[61] Türköz A, Tunçay E, Balci ŞT, et al. The effect of modified ultrafiltration duration on pulmonary functions and hemodynamics in newborns and infants following arterial switch operation. Pediatric critical care medicine : a journal of the Society of Critical Care Medicine and the World Federation of Pediatric Intensive and Critical Care Societies. 2014;15(7):600-607.
[62] Ziyaeifard M, Alizadehasl A, Aghdaii N, et al. The effect of combined conventional and modified ultrafiltration on mechanical ventilation and hemodynamic changes in congenital heart surgery. Journal of research in medical sciences : the official journal of Isfahan University of Medical Sciences. 2016;21(1):113.
[63] Ziyaeifard M, Alizadehasl A, Massiumi G. Modified Ultrafiltration During Cardiopulmonary Bypass and Postoperative Course of Pediatric Cardiac Surgery. Red Cardiovasc Med. 2014; 3(2):e17830.
[64] Heath M, Raghunathan K, Welsby I, Maxwell C. Using zero balance ultrafiltration with dialysate as a replacement fluid for hyperkalemia during cardiopulmonary bypass. The journal of extra-corporeal technology. 2014;46(3):262.
[65] Hein OV, Von Heymann C, Morgera S, Konertz W, Ziemer S, Spies C. Thoughts and progress. Artificial Organs. 2005;29(6):507-510.
[66] Huang H, Yao T, Wang W, et al. Continuous ultrafiltration attenuates the pulmonary injury that follows open heart surgery with cardiopulmonary bypass. The Annals of Thoracic Surgery. 2003;76(1):136.
[67] Journois D, Isreael-Beit D, Pourard P, et al. High volume, Zero-balanced Hemofiltration to Reduce Delayed Inflammatory Response to Cardiopulmonary Bypass in Children. Anesthesiology. 1996;85:965-76.
[68] Song L, Yinglong L, Jinping L. Effects of zero-balanced ultrafiltration on procalcitonin and respiratory function after cardiopulmonary bypass. Perfusion. 2007;22(5):339-343.
[69] Tallman RD, Dumond M, Brown D. Inflammatory mediator removal by zero-balance ultrafiltration during cardiopulmonary bypass. Perfusion. 2002;17(2):111-115.
[70] Zhu X, Ji B, Wang G, Liu J, Long C. The effects of zero-balance ultrafiltration on postoperative recovery after cardiopulmonary bypass: A meta-analysis of randomized controlled trials. Perfusion. 2012;27(5):386-392.

Standard 17: **Level of Readiness for Procedures that may require cardiopulmonary bypass**

Standard 17.1: Procedures identified preoperatively to be at elevated risk of requiring conversion to cardiopulmonary bypass (CPB) shall have a protocol for transition to CPB.

Standard 17.2: One Perfusionist shall be assigned for each such procedure.

Standard 17.3: A heart-lung machine consisting of a sterile extracorporeal set-up and ancillary equipment (Ref: Appendix B) shall be readily available for the procedure.

Guideline 17.1: The level of readiness for utilizing CPB during a surgical procedure should be determined through consultation with the surgical team.

Guideline 17.2: A heart-lung machine consisting of a sterile extracorporeal set-up and ancillary equipment (Ref: Appendix B) should be readily available for emergency procedures or as part of disaster planning protocols.[71]

[71] Preparedness for Specific Types of Emergencies. Centers for Disease Control and Prevention (https://emergency.cdc.gov/planning/) (accessed November 30, 2016).

Standard 18: Staffing and On-call

Standard 18.1: At minimum, the “n+1” staffing model shall be utilized at all times, where “n” equals the number of operating/procedure rooms in use at any given time at a single site.[72, 73, 74, 75]

Guideline 18.1**:** An on-call Perfusionist should be present and clinically ready for unscheduled and emergency procedures within 60 minutes of being called.

---

[72] Generally, the minimum safe number of perfusion staff: defined as *N + 1,* where N equals the number of operating/procedure rooms in use at any given time at a single site. (Ref: UK Code of Practice http://www.scps.org.uk/index.php?option=com_content&task=view&id=34&Itemid=40 accessed 14th October 2016)). If three operating/procedure rooms are concurrently in use then the minimum safe number of clinical perfusionists available to cover this level of activity is deemed to be four. Non-qualified staff members (e.g students or staff who have not completed training adequate to meet the requirements of the activity.) must not be included in calculating the minimum safe number of staff.

[73] Conliffe JA, Riley JB, Clutter J, Wolf K, Murtha S. A report of perfusion staffing survey: Decision factors that influence staffing of perfusion teams. The journal of extra-corporeal technology. 2007;39(4):249.

[74] Lawson DS, Darling EM, Collins K, Smigla GR, Shearer IR. Staffing issues at open-heart centers offering both pediatric and adult perfusion service: 1998 survey results. The journal of extra-corporeal technology. 1999;31(2):91.

[75] Stammers AH, Mejak BL. An update on perfusion safety: Does the type of perfusion practice affect the rate of incidents related to cardiopulmonary bypass? Perfusion. 2001;16(3):189-198.

Standard 19: Duty Hours

Standard 19.1: In order for the Perfusionist to ensure proper provision of care, he/she shall receive an adequate rest period between scheduled work hours.[76]

Guideline 19.1: The Perfusionist should receive a minimum of 8 hours of rest period for every 16-hour consecutive work period.

---

[76] 10.0 Tiredness and European Working Time Directive (EWTD). The Society of Clinical Perfusion Scientists of Great Britain and Ireland *and* The College of Clinical Perfusion Scientists of Great Britain and Ireland Standards of Practice Document
http://www.scps.org.uk/index.php?option=com_content&task=view&id=25&Itemid=40 (accessed November 30, 2016)

Standard 20: Quality Assurance and Improvement

Standard 20.1: The Perfusionist shall actively participate in both institutional and departmental quality assurance and improvement programs.

Guideline 20.1: The Perfusionist should collect data concerning the conduct of perfusion via a clinical registry or database.

Guideline 20.2: The Perfusionist should use such data for quality assurance, and improvement projects.[77, 78]

[77] Warren CS, DeFoe GR, Groom RC, Pieroni JW, Groski CS, Morse CB, Connors EM, Lataille PJ, Ross CS, Likosky DS; J Extra Corpor Technol 2011: 43(2):58-63.
[78] Baker RA, Newland RF, Fenton C, McDonald M, Wilcox TW, Merry AF. J Extra Corpor Technol 2012: 44(1), 26-33.

Standard 21: Maintenance

Standard 21.1: The Perfusionist shall assure that properly maintained and functioning equipment is used in the conduct of cardiopulmonary bypass (CPB), including (but not limited to):

- Heart lung machine
  - Pumps
  - Timers
  - Pressure monitors
  - Temperature monitors
  - Low Level alarm
  - Air bubble detector(s)
  - Blood flow sensors
- Heater/Cooler
- Anesthetic vaporizer
- Oxygen Blender/Flow Meter
- Oxygen analyzer
- Ancillary Equipment
  - IABP
  - VAD device
  - Cell salvage device

Standard 21.2: Preventive maintenance on perfusion equipment shall be performed by appropriately trained and qualified manufacturer technicians, representatives or Bio-Medical technicians. Regularly scheduled maintenance shall be documented by the perfusion department and/or Bio-Medical engineering staff. The interval of such maintenance shall be consistent with manufacturer recommendations, applicable external accrediting agency guidelines and institutional requirements.

Standard 21.3: The organization shall follow a protocol for perfusion equipment failures.[79]

Standard 21.4: Appropriate backup perfusion supplies shall be readily available.

Standard 21.5: The organization shall follow a protocol for acknowledging and addressing perfusion equipment notices (e.g., recalls, warnings, and advisories).

[79] New CMS & Joint Commission Regulations on Medical Equipment Maintenance: Taking the Smart Approach to Compliance. ABM Healthcare Support Services. https://www.abm.com/documents/white-papers/hss_new_cms_c-suite_whitepaper_081214.pdf (Accessed November 30, 2016)

Relevant Publications

American Society of Extra-Corporeal Technology. Perfusion practice survey, September, 1993. *Perfusion Life* 1994; **11**: 42–45.

American Society of Extra-Corporeal Technology. Guidelines for perfusion practice. *Perfusion Life* 1995; **12**: 20–22.

American Society of Extra-Corporeal Technology. Members accept essentials; approve revised code of ethics. *Perfusion Life* 1993; **10**: 14.

Kurusz M. Standards of practice in perfusion. *Perfusion* 1994; **9**: 211–15.

Aaron G Hill, Mark Kurusz. Perfusion Standards and Practice. *Perfusion* 1997; 12:251-255.

The Society of Clinical Perfusion Scientists of Great Britain and Ireland *and* The College of Clinical Perfusion Scientists of Great Britain and Ireland

- Standards of Practice Document. http://www.scps.org.uk/index.php?option=com_content&task=view&id=25&Itemid=40 (Accessed November 30, 2016)http://www.scps.org.uk/index.php?option=com_content&task=view&id=25&Itemid=40 (Accessed November 30, 2016)
- Codes of Practice Document. http://www.scps.org.uk/index.php?option=com_content&task=view&id=34&Itemid=40 (Accessed November 30, 2016)

The Australian and New Zealand College of Perfusion. Regulations and Guidelines for Perfusionists. (http://esvc000803.wic050u.server-web.com/Documents/ANZCP%20Regulations.pdf Accessed November 30, 2016

Appendix A: Patient information

1. Medical Record Number
2. Patient Surname, first name
3. Demographics
    a. Age (DOB)
    b. Gender
    c. Height
    d. Weight
    e. Body surface Area (BSA)
4. Blood Type
5. Laboratory Data
    a. Hemoglobin/Hematocrit
    b. Predicted Hematocrit on Bypass
    c. White Blood Cell Count
    d. Platelet Count
    e. aPTT
    f. Na
    g. K+
    h. BUN/CR
    i. Glucose
    j. Other Relevant Lab values
6. Patient Allergies
7. Planned Procedure
8. Medical History/Risk Factors (recommended)
    a. Cardiovascular
    b. Pulmonary
    c. Renal
    d. Neurologic
    e. GI/Endocrine

Appendix B: Information sufficient to accurately describe the procedure, personnel, and equipment

1. Date of Procedure
2. Type of Procedure
3. Perfusionist(s) Name
   a) Detail to clearly demonstrate the Perfusionist in charge of the case at all times.
4. Surgeon(s) Name
5. Anesthesiologist(s) Name
6. Nurse (s) name
7. Operating Room Number
8. Comments/Events (recommended)
9. Equipment
   a) Heart Lung Machine
   b) Cell Salvage (autotransfusion) Device
   c) Heater/Cooler

   Note: Items A-C must be uniquely identified (e.g. Pump 1, 2, 3 etc.) The related serial numbers for each component (e.g. roller pumps, vaporizer, blender, etc) are documented and stored locally.
10. Disposables
    a) Oxygenator
    b) Cardiotomy reservoir
    c) Tubing pack/Arterial line filter
    d) Centrifugal pump head
    e) Cardioplegia Delivery System
    f) Cell Salvage (autotransfusion)
    g) Ultrafiltration Device
    h) Arterial Cannula
    i) Venous Cannula
    j) Cardioplegia Cannula
    k) Sump/vent(s)

Note: Manufacturer, model, serial and/or lot numbers should be documented with items a-k.

Appendix C: Patient physiological and Perfusionist practice parameters documented at a frequency determined by institutional protocol.

1. Blood Flow Rates (RPM)
2. Arterial Blood Pressure
3. Arterial Line Pressure
4. Central Venous/Pulmonary Artery Pressure
5. Vacuum Assist Venous Return (VAVR)
   a) VAVR pressure
   b) Venous Inlet Pressure (VIP)
6. Arterial/Venous Blood Gases
7. Venous Oxygen Saturation
8. Patient Temperatures, including:
   a) Patient core (at least one)
      i. Nasopharyngeal
      ii. Bladder
      iii. Esophageal
      iv. Rectal
      v. Tympanic
   b) Optional
      i. Myocardium
9. CPB temperatures:
      i. Venous return blood
      ii. Arterial blood inflow
   a) Optional
      i. Water bath(s)
10. Oxygenator gases including gas flow rate and concentration(s) CO2 flow rate
11. Input fluid volumes including:
   a) Prime
   b) Blood Products
   c) Asanguineous Fluids
   d) Cardioplegic Solution
   e) Autologous Components
12. Cardioplegia
   a) Solution (ratio)
   b) Route
   c) Flow
   d) Pressure
   e) Temperature
   f) Volume

13. Output Fluid Volumes, including:

a) Urine output
b) Ultrafiltrate

14. Medications and/or inhalational anesthetic agents administered via extracorporeal circuit.

Appendix D: Blood gas, electrolyte and anticoagulation monitoring results

1. Blood gases
   a) pO_2
   b) pCO_2
   c) pH
   d) Base excess
   e) Bicarbonate concentration
   f) Saturation
   g) Potassium concentration
   h) Ionized calcium concentration
   i) Sodium concentration
   j) Lactate
   k) Glucose
   l) Hemoglobin/hematocrit
2. Activated Clotting Times (ACT) and/or Heparin/Protamine Assay Results and/or Thromboelastography Results

Appendix E: Regulatory documents, Revision 2016*

REGULATORY CITATION LEGEND

Regulations, Standards and Guidelines Resources	Citation Prefix
AABB Standards for Perioperative Autologous Blood Collection and Administration (6th Edition 2014)	**AABB**
College of American Pathologists (7/28/2015 Checklists)	**CAP**
Center for Improvement in Healthcare Quality (April 2016)	**CIHQ**
Centers for Medicare & Medicaid Conditions of Participation (CoP) – Hospitals (Title 42 Part 482)	**CMS-H**
CLIA Laboratory Regulations	**CMS-L**
Commission on Office Laboratory Accreditation (January 2016)	**COLA**
Healthcare Facility Accreditation Program (2015 v2)	**HFAP**
National Integrated Accreditation for Healthcare Organizations (Rev 11 6-17-2014)	**NIAHO**
International Organization for Standardization (Standard 9001:2008)	**ISO 9001**
Joint Commission Hospital Accreditation Standards 2016	**TJC-H**
Joint Commission Laboratory Accreditation Standards 2016	**TJC-L**

Please note, the ISO 9001 standards are included due to the link between NIAHO Accreditation and the requirement for the hospital to become either ISO Compliant or Certified.

Standard/Guideline	*Regulations, Standards and Guidelines Resources*	***Section***
Standard 1.1	*AABB*	*1.3, 6.0, 6.1.1*
	CAP-C	*COM.10000*
	CAP-G	*GEN.20374, GEN.20375*
	CMS-H	*§482.11*
	HFAP	*30.00.09*
	NIAHO	*QM.1_SR.1a(2); QM.3; GB.1_SR.1a; SS.1*
	ISO 9001	*4.1; 4.2; 4.2.1; 4.2.2; 5.1*
	TJC-HAP	*LD.04.01.07;LD.04.01.07_EP2; LD.04.04.07_EP1–EP3; NS.02.02.01_EP3; NS.02.03.01*
	TJC-L	*DC.01.01.01_EP1-EP3; DC.02.02.01_EP1-EP4*
Standard 1.2 • Dot point 1	*AABB*	*1.1.1; 1.3; 1.4; 6.0; 6.1 (6.1.1, 6.1.3)*
	CAP-C	*COM.10000; COM.10200*
	CAP-G	*GEN.20375*
	CIHQ	*GL-4*
	CMS – L	*§493.1200 (a-c)*
	COLA	*ORG 11 E; ORG 12 R; LDR 3 E; LDR 5 E*
	HFAP	*30.00.09*
	NIAHO	*NS.2_SR.3*
	ISO 9001	*4.2.3*
	TJC–HAP	*LD.04.01.07_EP1; LD.04.04.07_EP4; NR.02.03.01_EP1-EP2;*

	TJC-L	*DC.02.01.01*
• Dot point 2	*AABB*	*6.1.4 (biennial)*
	CAP-C	*COM.10100 (biennial)*
	CIHQ	*GL-4 (triennial)*
	COLA	*ORG 15 R (annual)*
	NIAHO	*QM.5 (annual), SM.3_SR.6*
	ISO 9001	*4.2.3, 5.6.1*
Guideline 1.1		
	AABB	*1.3.1, 5.4.2.2.1*
	CAP-C	*COM.10000*
	NIAHO	*QM.5*
	ISO-9001	*1.2*
Standard 2.1		
	AABB	*2.1; 2.1.1; 2.1.3*
	CAP-G	*GEN.54400, GEN.54750, GEN.55500*
	CAP-P	*POC.06800*
	CIHQ	*GL-3(G), HR-3(C), HR-4(E),MS-3(E), MS-5(B)*
	CMS-H	*§482.11(c), §482.23(3), §482.23(5), §482.51(4)*
	CMS-L	*§493.1423(e), §493.1423*
	COLA	*PER 2 E, PER 3 R, QC 31*
	HFAP	*01.00.04, 03.00.02, 03.01.06, 15.02.39, 16.00.04, 16.00.11, 18.00.06, 30.00.05,*
	NIAHO	*GB.1_SR.1c, NS.1, SM.1, SM.2, SS.3_SR.1*
	ISO 9001	*6.2.1, 6.2.2*
	TJC-HAP	*HR.01.02.01, HR.01.02.05, HR.01.06.01*
	TJC-L	*DC.02.02.01_EP1, HR.01.02.05_EP1-EP3, EP6, HR.01.02.07_EP1-EP2*

Standard 2.2		
	AABB	*2.1.3, 2.1.3.1*
	CAP-G	*GEN.55500, GEN.57000*
	CAP-P	*POC.06910*
	CIHQ	*HR-3(C)*
	CMS-H	*§482.23(3)*
	CMS-L	*§493.1235, §493.1423*
	COLA	*PER 5 R, QC 31*
	NIAHO	*SM.7_SR.1, SM.7_SR.2, SS.3_SR.1*
	TJC-HAP	*HR.01.06.01, HR.01.07.01 (EP1, EP2, EP5)*
	TJC-L	*HR.01.07.01_EP1-EP2*
Standard 2.3		
	AABB	*2.1.4*
	CAP-G	*GEN.54200*
	CIHQ	*MS-3(E)*
	CMS-L	*§493.557(a)(3)(iii)*
	COLA	*PER 6 R*
	HFAP	*01.00.04, 03.00.02, 16.00.06*
	NIAHO	*MS.10, SM.7_SR.6*
	ISO 9100	*6.2.2(e)*
	TJC-HAP	*HR.01.05.03*
	TJC-L	*HR.01.05.03_EP1, EP4-EP7*
Standard 2.5		
	AABB	*2.1.1, 2.1.2, 2.1.3, 2.1.4*
	CAP-G	*GEN.54200, GEN.54400, GEN.54750, GEN.55500, GEN.57000*
	CIHQ	*GL-3(G), HR-3(C), HR-4(E), MS-3(E), MS-5(B)*

	CMS-L	*§493.1423(e), §493.1423, §493.1235, §493.1423, §493.557(a)(3)(iii)*
	COLA	*PER 2 E, PER 3 R, PER 5 R, QC 31*
	HFAP	*01.00.04, 03.00.02, 03.01.06, 15.02.39, 16.00.04, 16.00.11, 18.00.06*
	NIAHO	*GB.1_SR.1c*
	ISO 9001	*6.2.1 (Note), 6.2.2*
	TJC-HAP	*HR.01.05.03_EP1, EP4*
	TJC-L	*HR.01.05.03_EP1, EP4-EP7*

Guideline 2.2		
	CMS-H	*§482.51(3)*
	HFAP	*18.00.07, 30.00.04*
	NIAHO	*SS.2_SR.3*
	ISO 9001	*6.2.1 (Note), 6.2.2(d)*
Standard 3.1		
	CIHQ	*NS-3*
	CMS-H	*§482.23(b)(4)*
	HFAP	*10.00.03; 10.01.26; 10.01.28; 16.00.10; 26.00.08; 26.0.11; 27.01.18*
	NIAHO	*NS.3_SR.1*
	TJC- HAP	*PC.01.03.01_EP1, EP3; PC.02.02.01_EP1; PC.02.02.01_EP1-EP2; UP.01.03.01_EP1-EP5*
Standard 3.2		
	TJC- HAP	*PC.02.02.01_EP1-EP2*
	TJC-L	*DC.03.03.01_EP1*
Guideline 3.2		
	AABB	*5.2.3*
	HFAP	*16.01.03, 16.01.04, 16.01.05*
	NIAHO	*MM.4_SR.2-SR.4*
	TJC- HAP	*LD.03.04.01_EP1; LD.03.04.02_EP3; LD.03.04.01_EP5*
Standard 4.1	*AABB*	*5.1.6.1; 6.2; 6.2.1*
	CAP-G	*GEN.20377*
	CAP-P	*POC.04400*
	CIHQ	*MR-4; OI-8; AN-2*
	CMS-H	*§482.24*
	HFAP	*10.00.03; 10.01.01; 10.01.02;*

	NIAHO	*SS.6; AN.3; MR.2; MR.3_SR.1; MR.5; MR.7*
	ISO 9001	*4.2.1(c), 4.2.1(d)*
	TJC-H	*RC.01.01.01_EP1; RC.01.05.01*
Standard 4.2		
Dot point 1, Appendix A	*AABB*	*6.2; 6.2.1*
	CAP-P	*POC.04400*
	CIHQ	*OI-7; OI-8; AN-2*
	CMS-H	*§482.24*
	HFAP	*30.00.18*
	NIAHO	*SS.6; MR.5*
	TJC-H	*RC.01.01.01_EP5*
Dot point 2, Appendix B	*AABB*	*6.2.4*
	CIHQ	*OI-7*
	CMS-H	*§482.51*
	HFAP	*10.01.03; 30.00.18*
	NIAHO	*SS.6; SS.8 (SR.1 - SR.3); AN.3 (SR.2c, SR.2d1); MR.5; MR.7*
	TJC-H	*RC.01.01.01; RC.02.01.01*
Dot point 3, Appendix C	*AABB*	*6.2.4*
	CIHQ	*AN-2*
	CMS-H	*§482.24; §482.52*
	HFAP	*0.01.03; 30.00.19*
	NIAHO	*SS.6; SS.8 (SR.1 – SR.3); AN.3 (SR.2c, SR.2d1); MR.5_SR.1c; MR.7*
	TJC-H	*RC.01.01.01_EP7*

Dot point 4, Appendix D	*CAP-C*	*COM.29950*
	CIHQ	*AN-2*
	CMS-H	*§482.24*
	HFAP	*10.01.03; 30.00.19*
	NIAHO	*SS.6; SS.8 (SR.1 - SR.3); AN.3 (SR.2c, SR.2d1); MR.5_SR.1c; MR.7*
	TJC-H	*RC.01.01.01_EP7*
Dot point 5		
	AABB	*6.2.4*
	CAP-P	*POC.04700*
	CIHQ	*MR-4*
	CMS-H	*§482.23; §482.24; §482.51*
	HFAP	*10.01.03; 10.01.04; 30.00.19*
	NIAHO	*SS.8_SR.2; MR.5 (SR.2b, SR.4, SR.4a); MR.6*
	TJC-H	*RC.01.02.01; RC.02.03.07_EP1*
Guideline 4.1	*NIAHO*	*MR.5 (SR.2 – SR.5)*
Guideline 4.2	*AABB*	*5.2.3*
	CIQH	*MR-4*
	CMS-H	*§482.23; §482.24; §482.51*
	COLA	*WAV 9 R*
	HFAP	*10.01.03; 10.01.04; 30.00.19*
	NIAHO	*MR.5 (SR.2b, SR.3, SR.4, SR.5)*
	TJC-H	*RC.01.02.01; RC.02.03.07*
Guideline 4.3	*AABB*	*6.2.8; 6.2.9*
	CAP-G	*GEN.20377; 20425*
	CIHQ	*MR-3*
	CMS-H	*§482.23; §482.24*

	CMS-L	*§493.1101; §493.1105*
	COLA	*WAV 9 R*
	HFAP	*10.00.03*
	NIAHO	*MR.3 (SR.1 – SR.2)*
	TJC-H	*RC.01.05.01*
	TJC-L	*DC.02.04.01*
Standard 5.1	*TJC-H*	*UP.01.01.01*
Standard 6	*NIAHO*	*SS.1; AS.1*
	TJC-H	*NPSG.06.01.01; LD.04.04.05*
Standard 6.1	*CIQH*	*QS-9*
	TJC-H	*NPSG.06.01.01*
Standard 6.2	*CIQH*	*QS-9*
	TJC-H	*NPSG.06.01.01*
Standard 6.3	*CIQH*	*QS-9*
	TJC-H	*NPSG.06.01.01*
Standard 6.4	*CIQH*	*QS-9*
	TJC-H	*NPSG.06.01.01*
Standard 6.7	*CIQH*	*QS-9*
	TJC-H	*NPSG.06.01.01*
Guideline 6.2	*CIQH*	*QS-9*
	TJC-H	*NPSG.06.01.01*
Standard 7	*CIHQ*	*AN-2 E*
	HFAP	*15.02.17*
	NIAHO	*AS.3_SR.2d(1)*
	TJC-H	*PC.01.02.01*
Standard 8	*TJC*	*NPSG.03.05.01*

Standard 8.1	*CIHQ*	*NS-3*
	CMS-H	*§482.23(b)(4)*
	HFAP	*10.00.03; 10.01.26; 10.01.28; 16.00.10; 26.00.08; 26.0.11; 27.01.18*
	NIAHO	*NS.3_SR.1*
	TJC- HAP	*PC.01.03.01_EP1, EP3; PC.02.01.01_EP1; PC.02.02.01_EP1-EP2; UP01.03.01_EP1-EP5*
Standard 9.2	*CAP-C*	*COM.40610;*
	CAP-P	*POC.07300; POC.07512; POC.07540; POC08980; POC.09035; POC.09090; POC09145*
	COLA	*LDR 2 E; QC 1 E; CA 1 R*
	TJC-L	*EC.02.04.03; QSA.02.02.01; QSA.02.03.01*
Standard 9.3	*CAP-G*	*GEN.41304;*
	CAP-P	*POC.04400; POC.04700*
	COLA	*LIS 2.7; APM 18 (PST) R*
	TJC-L	*DC.02.03.01*
Guideline 9.1	*CAP-G*	*GEN.41304; GEN.41345*
	TJC-L	*QSA.02.10.01; QSA.06.01.01; DC.02.03.01*
Standard 10.1	*CIHQ*	*NS-3*
	CMS-H	*§482.23(b)(4)*
	HFAP	*10.00.03; 10.01.26; 10.01.28; 16.00.10; 26.00.08; 26.0.11; 27.01.18*
	NIAHO	*NS.3_SR.1*
	TJC- HAP	*PC.01.03.01_EP1, EP3; PC.02.01.01_EP1; PC.02.02.01_EP1-EP2; UP.01.03.01_EP1-EP5*
Standard 11.1	*CIHQ*	*NS-3*
	CMS-H	*§482.23(b)(4)*

	HFAP	*10.00.03; 10.01.26; 10.01.28; 16.00.10; 26.00.08; 26.0.11; 27.01.18*
	NIAHO	*NS.3_SR.1*
	TJC- HAP	*PC.01.03.01_EP1, EP3; PC.02.01.01_EP1; PC.02.02.01_EP1-EP2; UP.01.03.01_EP1-EP5*
Standard 11.2	*CIHQ*	*NS-3*
	CMS-H	*§482.23(b)(4)*
	HFAP	*10.00.03; 10.01.26; 10.01.28; 16.00.10; 26.00.08; 26.0.11; 27.01.18*
	NIAHO	*NS.3_SR.1*
	TJC- HAP	*PC.01.03.01_EP1, EP3; PC.02.01.01_EP1; PC.02.02.01_EP1-EP2; UP.01.03.01_EP1-EP5*
Guideline 11.1	*AABB*	*1.3.1; 5.4.2.2.1*
	CAP-C	*COM.10000*
	NIAHO	*QM.5*
	ISO-9001	*1.2*
Standard 14.1	*AABB*	*5.2.3*
	HFAP	*16.01.03; 16.01.04; 16.01.05*
	NIAHO	*MM.4_SR.2-SR.4;*
	TJC- HAP	*LD.03.04.01_EP1; LD.03.04.02_EP3; LD.03.04.01_EP5*
Standard 17.1	*CIHQ*	*NS-3*
	CMS-H	*§482.23(b)(4)*
	HFAP	*10.00.03; 10.01.26; 10.01.28; 16.00.10; 26.00.08; 26.0.11; 27.01.18*
	NIAHO	*NS.3_SR.1*
	TJC- HAP	*PC.01.03.01_EP1,EP3; PC.02.01.01_EP1; PC.02.02.01_EP1-EP2; UP.01.03.01_EP1-EP5*

Guideline 17.1	*CIHQ*	*NS-3*
	CMS-H	*§482.23(b)(4)*
	HFAP	*10.00.03; 10.01.26; 10.01.28; 16.00.10; 26.00.08; 26.0.11; 27.01.18*
	NIAHO	*NS.3_SR.1*
	TJC- HAP	*PC.01.03.01_EP1, EP3; PC.02.01.01_EP1; PC.02.02.01_EP1-EP2; UP.01.03.01_EP1-EP5*
Standard 20.1	*AABB*	*5.1.2; 8.2; 9.0*
	CAP-C	*COM.04000; COM.04200*
	CAP-G	*GEN.13806*
	CIHQ	*QA-1*
	CMS-H	*§482.21*
	CMS-L	*§493.1200; §493.1230; §493.1239*
	COLA	*QA 1 E*
	HFAP	*12.00.00; 12.00.04*
	NIAHO	*QM.1 (SR.1-SR.2); QM.2; QM.3; QM.6*
	ISO 9001	*8.1; 8.2.1; 8.5.1; 8.5.3*
	TJC-H	*LD.04.04.01 (EP1-EP4); PI.01.01.01 (EP1-EP3)*
	TJC-L	*PI.01.01.01*
Guideline 20.1	*AABB*	*5.1.2.1; 5.1.2.2; 8.3; 9.0; 9.1*
	CAP-C	*COM.04200*
	CAP-G	*GEN.20316*
	CIHQ	*QA-2 (A-C)*
	CMS-H	*§482.21*
	COLA	*QA 2 E*
	HFAP	*12.00.01; 12.00.04*
	NIAHO	*QM.5; QM.7*
	ISO 9001	*8.2.3*

	TJC-H	*PI.01.01.01 (EP*
	TJC-L	*PI.02.01.01*
Guideline 20.2	*AABB*	*5.1.2.1; 5.1.2.2; 8.3; 9.0; 9.1; 9.2*
	CAP-G	*GEN.16902; GEN.20316*
	CIQH	*QA-2 (D-E); QA-4; QA-5*
	CMS-H	*§482.21*
	CMS-L	*§493.1200; §493.1230; §493.1239*
	COLA	*QA 3 R; QA 4 R; QA 5 R*
	HFAP	*12.00.02; 12.00.04; 12.01.02*
	NIAHO	*QM.7; QM.8*
	ISO 9001	*8.2.2; 8.3; 8.4; 8.5.1; 8.5.2; 8.5.3*
	TJC-H	*PI.02.01.01; PI.03.01.01*
	TJC-L	*PI.03.01.01*
Standard 21.1	*AABB*	*3.5; 3.5.1; 3.5.1.1*
	CIHQ	*CE-8_A*
	CMS-H	*§482.26; §482.41; §482.53*
	CMS-L	*§493.1101; §493.1254*
	HFAP	*11.06.09; 11.06.10*
	NIAHO	*PE.1; PE.7*
	TJC-H	*EC.02.04.01; EC.02.04.03*
	TJC-L	*EC.02.04.01; EC.02.04.03*
Standard 21.2	*AABB*	*3.5; 3.5.1; 3.5.1.1*
	CIHQ	*CE-8 (B, D)*
	CMS-H	*§482.26; §482.41; §482.53*
	CMS-L	*§493.1101; §493.1254*
	HFAP	*11.06.09*
	NIAHO	*PE.1; PE.7_SR.6*
	TJC-H	*EC.02.04.01; EC.02.04.03*

	TJC-L	*EC.02.04.01; EC.02.04.03*
Standard 21.3	*CIQH*	*CE-8 (M, N)*
	NIAHO	*PE.7 (SR.4-SR.5)*
	TJC-H	*EC.02.04.01_EP9*
	TJC-L	*EC.02.04.01; EC.02.04.03*
Standard 21.4	*NIAHO*	*PE.7*
Standard 21.5	*HFAP*	*08.00.06; 25.00.00*
	CMS-H	*§482.25*
	NIAHO	*PE.1; PE.3; PE.7*
	TJC-H	*EC.02.02.01_EP11; MM.05.01.017*
	TJC-L	*EC.02.02.01_EP11*

Appendix F: Perfusion Checklist

Perfusion Checklist

Patient ID ______________________

Check each item when completed, sign and date. If not applicable, ~~draw line through.~~ ***Bold italicized items for expedited set-up.***

- **PATIENT**
  - ☐ ***Patient identity confirmed***
  - ☐ ***Procedure confirmed***
  - ☐ ***Blood type, antibodies confirmed***
  - ☐ ***Allergies checked***
  - ☐ Blood bank number confirmed
  - ☐ Medical record number confirmed
  - ☐ Chart reviewed
- **STERILITY/CLEANLINESS**
  - ☐ ***Components checked for package integrity/expiration***
  - ☐ Equipment clean
  - ☐ Heat exchanger(s) leak-tested
- **PUMP**
  - ☐ ***Occlusion(s) set***
  - ☐ ***Speed controls operational***
  - ☐ ***Flow meter in correct direction and calibration***
  - ☐ ***Flow rate indicator correct for patient and/or tubing size***
  - ☐ ***Rollers rotate freely***
  - ☐ Pump head rotation smooth and quiet
  - ☐ Holders secure
  - ☐ Servoregulated connections tested
- **ELECTRICAL**
  - ☐ ***Power cord(s) connection(s) secure***
  - ☐ ***Servoregulation connections secure***
  - ☐ Batteries charged and operational
- **CARDIOPLEGIA**
  - ☐ ***System debubbled and operational***
  - ☐ System leak-free after pressurization
  - ☐ Solution(s) checked

- **GAS SUPPLY**
  - ☐ ***Gas line(s) and filer connections secure***
  - ☐ ***Gas exhaust unobstructed***
  - ☐ ***Source and appropriate connections of gas(es) confirmed***
  - ☐ ***Flow meter / gas blender operational***
  - ☐ Hoses leak-free
  - ☐ Anesthetic gas scavenge line operational
- **COMPONENTS**
  - ☐ ***System debubbled and operational***
  - ☐ ***Connections / stopcocks / caps secure***
  - ☐ ***Appropriate lines claimed / shunts closed***
  - ☐ ***Tubing direction traced and correct***
  - ☐ ***Patency of arterial line / cannula confirmed***
  - ☐ No tubing kinks noted
  - ☐ One-way valve(s) in correct direction
  - ☐ Leak-free after pressurization
- **SAFETY MECHANISMS**
  - ☐ ***Alarms operational, audible and engaged***
  - ☐ ***Arterial filter / bubble trap debubbled***
  - ☐ ***Cardiotomy / hardshell venous reservoir(s) vented***
  - ☐ ***Vent(s) tested***
  - ☐ Venous line occluder(s) calibrated and tested
  - ☐ Devices securely attached to console
- **ASSISTED VENOUS RETURN**
  - ☐ ***Cardiotomy positive-pressure relief valve present***
  - ☐ ***Negative- pressure relief valve unobstructed***
  - ☐ Vacuum regulator operational
- **MONITORING**
  - ☐ ***Circuit / patient temperature probes placed***
  - ☐ Pressure transducers / monitors calibrated and on proper scales
  - ☐ Inline sensors calibrated
  - ☐ Oxygen analyzer calibrated
- **ANTICOAGULATION**
  - ☐ ***Heparin time and dose confirmed***
  - ☐ Anticoagulation tested and reported

- **TEMPERATURE CONTROL**
  - ☐ ***Water source(s)connected and operational***
  - ☐ Temperature range(s) tested and operational
  - ☐ Water lines unobstructed
- **SUPPLIES**
  - ☐ ***Tubing clamps available***
  - ☐ Drugs available and properly labeled
  - ☐ Solutions available
  - ☐ Blood products available
  - ☐ Sampling syringes / laboratory tubes available
  - ☐ Anesthetic vaporizer correct
  - ☐ Vaporizer operational and filled
- **BACKUP**
  - ☐ ***Hand cranks available***
  - ☐ ***Duplicate circuit components / hardware available***
  - ☐ Emergency lighting / flashlight available
  - ☐ Backup full oxygen tank with flow meter available
  - ☐ Ice available
- **EMERGENT RESTART OF BYPASS**
  - ☐ ***Heparin time and dose confirmed***
  - ☐ ***Components debubbled***
  - ☐ ***Gas flow confirmed***
  - ☐ ***Alarms reengaged***
  - ☐ Water source(s) connected
- **TERMINATION CHECKLIST**
  - ☐ ***Venous assist off / cardiotomy / venous reservoirs vented***
  - ☐ ***Shunt(s) closed***
  - ☐ ***Vent(s) clamed / removed***
- **POSTBYPASS CHECKLIST**
  - ☐ ***Announce bypass terminated***
  - ☐ ***Arterial and venous lines clamped***
  - ☐ ***Arterial circuit bubble-free before transfusing perfusate***
  - ☐ Pump suction(s) off

Comments:

Signature: ____________________________
Date: _______________ Time: ___________

These perfusion checklists, or a reasonable equivalent, should be used in perfusion practice. This is a guideline, which tPerfusionists are encouraged to modify to accommodate difference in circuit design and variations in institutional clinical practice. Users should refer to manufacturers' information, including Instructions for Use, for specific procedures and/or precautions. AmSECT disclaims any and all liability and responsibility for injury and damages resulting from following this suggested checklist. Origination 1990; revision 2004 by AmSECT Quality Committee.