

American Society of ExtraCorporeal Technology
Standards and Guidelines
for 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.

Approach

In 2011, the AmSECT Board of Directors (BOD) requested the International Consortium for Evidence-Based Perfusion (ICEBP) subcommittee to review and update the Essentials and Guidelines. In 2013, the revision was completed and adopted by the membership, and a report of this work published in the Journal of Extracorporeal Technology (J Extra Corporeal Technol. 2013 Sep;45(3):156-66). In recognition of the developing role of extracorporeal support the BOD requested that the 2013 Standards and Guidelines be updated. The ICEBP undertook this review and shared the suggested revision with the BOD and the perfusion community at AmSECT's conferences in 2014 and 2015. **Based on feedback from conference attendees, and further review, the ICEBP submitted a revised document that was approved by the BOD and membership in 2017. As a continuation to improve quality and focus on patient safety the Standards and Guidelines have been updated for 2021.** With these goals in mind, the Standards and Guidelines will **continue to** be reviewed and updated as necessary or as deemed appropriate by AmSECT's BOD.

The 2021 update includes extensive modifications to existing standards (and their respective guidelines) to enhance their interpretation and use. In addition, the update includes the addition of Standard 19 that focuses on crisis management.

To facilitate the understanding of the Standards and Guidelines, we define important terms used throughout

the document. Unless otherwise stated, Standards and Guidelines are written for the perfusion department, with the intent to be disseminated and adopted across members of this team.

Definitions:

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

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 shall is used to indicate a mandatory requirement.

Should: In this document, the word should 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.

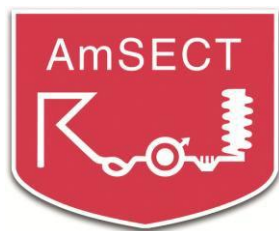
The term 'supervising physician' is intended to describe the physician responsible, at that given time, for the patient and their hemodynamics.

The word 'continuously' describes an action that occurs without ceasing, whereas the word 'continually' is intended to describe an action that recurs frequently or regularly.

Appendix: The appendices are presented as documents to help with institutional implementation of specified Standards and Guidelines. As such, appendices are meant solely as supporting material.

Disclaimer:

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.



American Society of ExtraCorporeal Technology
Standards and Guidelines
For Perfusion Practice

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Standard 1: Development of Institutionally-based Protocols

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.

Standard 1.3: Perfusion emergency protocols shall be accessible to help guide the user during an event.¹

Guideline 1.1: Deviation from protocol may be at the discretion of the **supervising physician** and should be documented in the perfusion record.

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¹ AmSECT Failure Mode and Effects Analysis examples: <https://www.amsect.org/page/fmea-archives>

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 **extracorporeal support procedures**.²
- 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.³
- Standard 2.4:** Support staff shall be available on site to assist the primary Perfusionist during **extracorporeal support** procedures.
- Standard 2.5:** ~~A process to educate, train, and annually evaluate perfusion staff shall be developed and followed.~~
- Standard 2.5:** **An outline detailing the onboarding process shall be developed in order to provide new hires with sufficient time to orient and safely perform perfusion related responsibilities. The onboarding process shall be documented and retained upon completion**
- 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 **extracorporeal support** procedures. Support staff may include a Perfusionist, nursing, technical, or non- technical staff.

² AmSECT recognizes that individual states may license Perfusionists based on other criteria. These laws supersede this standard.

³ American Board of Cardiovascular Perfusion, www.abcp.org/ (accessed **March 6, 2021**)

Standard 3: Communication

- Standard 3.1:** A patient-specific management plan for the **extracorporeal support** procedure shall be prepared and communicated to the surgical team either during the pre-operative briefing or prior to beginning the procedure.⁴
- Standard 3.2:** The primary Perfusionist shall use a set handoff protocol (e.g., SBAR- Situation, Background, Assessment, Communication) when transitioning the management of the case to a second Perfusionist.⁵
- Standard 3.3:** The primary Perfusionist shall participate in the post-procedure debrief with the surgical team.

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.⁶

Guideline 3.2: Protocol driven communication (e.g., closed-loop), should be utilized to acknowledge verbal commands, verify the content, and reduce ambiguity.^{7,8,9}

Guideline 3.3 **Topics that should be considered during the post-procedure debrief include, but are not limited to, communication, additional training, equipment or disposables issues, post-operative instructions, and safety events.**

Guideline 3.4 **Deviations from the intended treatment care plan should be documented and communicated to the supervising physician to allow for changes in the management plan.**

⁴ World Health Organization surgical safety checklist and implementation manual. World Health Organization, http://www.who.int/patientsafety/safesurgery/ss_checklist/en/ (accessed **March 6, 2021**)

⁵ 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 **March 6, 2021**)

⁶ Statement on use of cell phones in the operating room, **October 1, 2016**. Bulletin of the American College of Surgeons, <https://www.facs.org/~media/files/publications/bulletin/2008/2008%20september%20bulletin.ashx> (accessed **March 6, 2021**)

⁷ 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 Feb;139(2):312-9. doi: 10.1016/j.jtcvs.2009.10.048. PMID: 20106395.

⁸ 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 dramatic analysis. Soc Sci Med. 2009 Dec;69(12):1757-66. doi: 10.1016/j.socscimed.2009.09.054. Epub 2009 Oct 23. PMID: 19853344.

⁹ de Vries EN, Prins HA, Crolla RM, den Outer AJ, van Anel G, van Helden SH, Schlack WS, van Putten MA, Gouma DJ, Dijkgraaf MG, Smorenburg SM, Boormeester MA; SURPASS Collaborative Group. Effect of a comprehensive surgical safety system on patient outcomes. N Engl J Med. 2010 Nov 11;363(20):1928-37. doi: 10.1056/NEJMs0911535. PMID: 21067384.

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 supervising 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 the institution's policy for retaining electronic patient medical records.

Standard 5: Checklist

Standard 5.1: The Perfusionist shall use a checklist for each **extracorporeal support** procedure.¹⁰

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.¹¹ 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).

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¹⁰ 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 Jan 29;360(5):491-9. doi: 10.1056/NEJMs0810119. Epub 2009 Jan 14. PMID: 19144931.

¹¹ 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 **extracorporeal support** procedures.
- The pressure monitor shall be either servoregulated 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 **extracorporeal support** 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 **extracorporeal support** procedures utilizing a (hard-shell) reservoir.
- The level sensor shall be either servoregulated 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 **extracorporeal support procedures**.
- The temperature sensor shall include an audible and visual alarm to prevent high arterial outlet temperatures.¹²
- Standard 6.5:** An arterial-line filter, **external or integrated**, shall be employed during **extracorporeal support** procedures.
- Standard 6.6:** A one-way valve in the vent line shall be employed during **extracorporeal support** procedures.
- Standard 6.7:** A method for retrograde flow avoidance when using a centrifugal pump shall be employed during **extracorporeal support** 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 **extracorporeal support**

¹² Engelman R, Baker RA, Likosky DS, Grigore A, Dickinson TA, Shore-Lesserson L, Hammon JW. The Society of Thoracic Surgeons, The Society of Cardiovascular Anesthesiologists, and The American Society of ExtraCorporeal Technology: Clinical Practice Guidelines for Cardiopulmonary Bypass—Temperature Management during Cardiopulmonary Bypass. J Extra Corpor Technol. 2015 Sep;47(3):145-54. PMID: 26543248.

procedures.

Standard 6.9: Hand cranks shall be readily available during **extracorporeal support** procedures.

Standard 6.10: A back-up gas supply shall be available during **extracorporeal support** procedures.

Standard 6.11: **The extracorporeal support machine shall have a backup power source that allows for uninterrupted power supply during extracorporeal support procedures.**

Guideline 6.1: A ventilating gas oxygen analyzer should be employed during **extracorporeal support** procedures.

Guideline 6.2: A level sensor should be employed during **extracorporeal support** procedures utilizing a soft-shell reservoir.

- The level sensor should be either servoregulated 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.

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Standard 7: Monitoring¹³

- Standard 7.1:** Patient arterial blood pressure shall be monitored continuously during extracorporeal support procedures.¹⁴
- Standard 7.2:** Arterial line pressure shall be monitored continuously during extracorporeal support procedures.
- Standard 7.3:** Arterial blood flow shall be monitored continuously at a point in the extracorporeal support circuit where it accurately reflects the flow delivered to the patient during extracorporeal support procedures (e.g., distal to intra-circuit shunts).
- Standard 7.4:** Cardioplegia dose, delivery method, line pressure (antegrade), coronary sinus pressure (retrograde) and ischemic intervals shall be monitored continually during **extracorporeal support** procedures.
- Standard 7.5:** Patient and device temperatures shall be monitored continually during **extracorporeal support** procedures.
- Patient (e.g., nasopharyngeal, rectal, bladder, esophageal)
 - Heart lung machine (arterial, venous and cardioplegia)
- Heater cooler (H2O temperature)
- Standard 7.6:** Blood gas analyses shall be monitored continually or at regular intervals during **extracorporeal support** procedures (Appendix D).
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- Standard 7.7:** Hematocrit (or hemoglobin) shall be monitored continually during **extracorporeal support** procedures.
- Standard 7.8:** Oxygen fraction and gas flow rates shall be monitored continually during **extracorporeal support** procedures.
- Standard 7.9:** Venous oxygen saturation shall be monitored continually during **extracorporeal support** procedures.
- Guideline 7.1:** Carbon dioxide removal should be monitored continually during **extracorporeal support** procedures.
- Guideline 7.2:** Arterial oxygen saturation should be monitored continually during **extracorporeal support** procedures.

¹³ To be performed in conjunction with Standard 3.

¹⁴ Here, and throughout this document, 'continuously' describes an action that occurs without ceasing, whereas the word 'continually' is intended to describe an action that recurs frequently or regularly.

Guideline 7.3: The following patient pressures should be monitored during **extracorporeal support** procedures:

- Central venous pressure and/ or Pulmonary artery blood pressure, **if available**

Guideline 7.4: Continuous in-line blood gas monitoring should be used during **extracorporeal support** procedures.

Guideline 7.5:

- Cerebral oximetry should be used during **extracorporeal support** procedures.

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Standard 8: Anticoagulation

- Standard 8.1:** The Perfusionist, in collaboration with the supervising physician, shall define the intended anticoagulation management algorithm, including:
- Acceptable target and range for activated clotting time (ACT), considering relevant factors that include the variability in ACT measurement attributed to the measuring device's performance characteristics.
 - Monitoring and treating the patient's anticoagulation status before, during, and after the cardiopulmonary bypass period at a determined frequency.
 - Patient-specific initial heparin dosage using one of the following methods:
 - Weight
 - Dose Response Curve (automated or manual)
 - Blood Volume
 - Body Surface Area
 - Preparing alternative means of anticoagulation for when heparin is not suitable.

Guideline 8.1: 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 8.2: Additional doses of heparin during extracorporeal support procedures should be determined by using an appropriate anticoagulation test.¹⁵

Guideline 8.3:

- Heparin reversal management strategy should aim to limit over-exposure to protamine and should be confirmed by ACT and/or heparin/protamine titration.

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¹⁵ In patients requiring longer cardiopulmonary bypass (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). Reference: Society of Thoracic Surgeons Blood Conservation Guideline Task Force, Ferraris VA, Brown JR, Despotis GJ, Hammon JW, Reece TB, Saha SP, Song HK, Clough ER; Society of Cardiovascular Anesthesiologists Special Task Force on Blood Transfusion, Shore-Lesserson LJ, Goodnough LT, Mazer CD, Shander A, Stafford-Smith M, Waters J; International Consortium for Evidence Based Perfusion, Baker RA, Dickinson TA, FitzGerald DJ, Likosky DS, Shann KG. 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. PMID: 21353044.

Standard 9: Gas Exchange

Standard 9.1: Gas exchange shall be maintained during extracorporeal support procedures according to protocol, accounting for individual patient needs

Standard 9.2: **Indexed** Oxygen delivery and consumption calculations should be utilized to evaluate and optimize gas exchange.^{16,17,18}

- Oxygen Delivery: $DO2i = 10 \times CI \times CaO2$

Oxygen Consumption: $VO2i = 10 \times CI \times (CaO2 - CvO2)$

Where:

$CaO2$ (arterial oxygen content) = $(Hb \times 1.36 \times SaO2) + (0.0031 \times PaO2)$,

and

$CvO2$ (mixed venous oxygen content) = $(Hb \times 1.36 \times SvO2) + (0.0031 \times PvO2)$

CI = cardiac index

Hb = hemoglobin

SaO2 = arterial oxygen saturation

PaO2 = partial pressure of oxygen in arterial blood

SvO2 = venous oxygen saturation

PvO2 = partial pressure of oxygen in venous blood

Guideline 9.1: Point-of-Care testing should be considered to provide accurate and timely information for blood gas analysis.¹⁹

¹⁶ de Somer F, Mulholland JW, Bryan MR, Aloisio T, Van Nooten GJ, Ranucci M. O2 delivery and CO2 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. PMID: 21831302; PMCID: PMC3387634.

¹⁷ Justison G. Is Timing Everything? J Extra Corpor Technol. 2017 Jun;49(2):P13-P18. PMID: 28638165; PMCID: PMC5474897.

¹⁸ Newland RF, Baker RA. Low Oxygen Delivery as a Predictor of Acute Kidney Injury during Cardiopulmonary Bypass. J Extra Corpor Technol. 2017 Dec;49(4):224-230. PMID: 29302112; PMCID: PMC5737422.

¹⁹ 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/science-and-research/practice-guidelines/point-of-care-testing> (accessed March 6, 2021)

Standard 10: Blood Flow

Standard 10.1: Target blood flow rates shall be determined prior to **extracorporeal support** according to protocol.

Standard 10.2: The Perfusionist shall work closely with the ~~surgical care team~~ **supervising physician** to maintain targeted blood flow rate during **extracorporeal support** procedure.

Guideline 10.1: Appropriate blood flow rate should be determined by evaluation of:

- Acid base balance
- Anesthetic level
- Arterial blood pressure
- Cerebral oximetry
- Lactate burden
- Oxygen delivery and consumption (refer to Standard 9.2 for formula)
 - Venous pO₂
 - Arterial pO₂
 - Hemoglobin concentration
 - Arterial oxygen saturation
- Temperature
- Venous oxygen saturation

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Standard 11: Blood Pressure

Standard 11.1: The Perfusionist, in collaboration with the **surgical care team**, shall define and communicate the intended treatment algorithm for blood pressure management prior to **extracorporeal support** procedures, including acceptable ranges for blood pressure.²⁰

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²⁰ In many circumstances, the supervising physician may direct the perfusionist to modify the intended blood pressure management to address circumstances occurring during the extracorporeal support procedure.

Standard 12. Protamine and Cardiomy Suction.

Standard 12.1: Cardiomy suction shall be discontinued at the onset of protamine administration to avoid clotting within the **extracorporeal support** circuit.

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Standard 13: Blood Management

Standard 13.1: The Perfusionist shall utilize the timely and collaborative application of evidence-based medical and surgical concepts (see Guideline 13.1) designed to maintain hemoglobin concentration, optimize hemostasis, and minimize blood loss in an effort to improve patient outcome.²¹

Standard 13.2: The Perfusionist shall minimize the **extracorporeal support** circuit size to reduce prime volume.²⁰

Standard 13.3: The Perfusionist shall calculate, **prior to induction**, and communicate to the surgical team prior to initiating **extracorporeal support**, a patient's predicted post-dilutional hemoglobin or hematocrit.

Guideline 13.1: Blood management efforts should include the following.^{20, 22}

- Participate in pre-operative briefings (discussions) with the surgical care team (Standard 3.1) regarding transfusion strategies and target hematocrit values.
- Participation in a multidisciplinary blood management team.
- Minimize hemodilution by:
 - **Ultrafiltration**
 - Matching the size of the **extracorporeal support** circuit to the size of the patient
 - Autologous priming of **extracorporeal support** circuit, including retrograde arterial and/or venous antegrade priming
 - Biocompatible coating on the surface of all **extracorporeal support** circuitry
 - Perioperative blood cell recovery, **appropriate processing**, and reinfusion.

Extracorporeal support circuit blood salvage at the end of the procedure

Guideline 13.2: **Laboratory and** Point-of-Care hemostasis monitoring should be utilized to minimize blood loss. Monitoring may include:

- International normalized ratio
- Partial Thromboplastin time
- Prothrombin time
- Thrombin time

²¹ Society of Thoracic Surgeons Blood Conservation Guideline Task Force, Ferraris VA, Brown JR, Despotis GJ, Hammon JW, Reece TB, Saha SP, Song HK, Clough ER; Society of Cardiovascular Anesthesiologists Special Task Force on Blood Transfusion, Shore-Lesserson LJ, Goodnough LT, Mazer CD, Shander A, Stafford-Smith M, Waters J; International Consortium for Evidence Based Perfusion, Baker RA, Dickinson TA, Fitzgerald DJ, Likosky DS, Shann KG. 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. doi: 10.1016/j.athoracsur.2010.11.078. PMID: 21353044.

²² Task Force on Patient Blood Management for Adult Cardiac Surgery of the European Association for Cardio-Thoracic Surgery (EACTS) and the European Association of Cardiothoracic Anaesthesiology (EACTA), Boer C, Meesters MI, Milojevic M, Benedetto U, Bolliger D, von Heymann C, Jeppsson A, Koster A, Osnabrugge RL, Ranucci M, Ravn HB, Vonk ABA, Wahba A, Pagano D. 2017 EACTS/EACTA Guidelines on patient blood management for adult cardiac surgery. J Cardiothorac Vasc Anesth. 2018 Feb;32(1):88-120. doi: 10.1053/j.jvca.2017.06.026. Epub 2017 Sep 30. PMID: 29029990.

- Thromboelastography/Thromboelastometry
- Platelet count
- Platelet function analysis
 - Fibrinogen
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Standard 14: Level of Readiness for Procedures that may require extracorporeal support

Standard 14.1: Procedures identified preoperatively to be at elevated risk of requiring conversion to an **extracorporeal support** procedure shall have a protocol for transition to **such** procedures.

Standard 14.2: One Perfusionist shall be assigned for each such **standby** procedure.

Standard 14.3: A heart-lung machine consisting of a sterile extracorporeal set-up and ancillary equipment (Ref: Appendix B) shall be readily available for the procedure.

Standard 14.4: Assembly and maintenance of circuit shall be regulated according to institutional protocol in collaboration with infection control.

Guideline 14.1 The level of readiness for utilizing **extracorporeal support** during a surgical procedure should be determined through consultation with the surgical team.

Guideline 14.2: Measures relating to circuit hygiene should be weighed up against patient safety, legal risk, costs, and feasibility. The result of the consultation is enforced at the local level by means of protocols.

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Standard 15: Staffing and On-call

- Standard 15.1** The “n+1” staffing model **shall** be utilized at all times, where “n” equals the number of operating/procedure rooms **requiring cardiopulmonary bypass** at any given time.²³
- Standard 15.2:** An on-call Perfusionist ~~should~~ **shall** be present and clinically ready for unscheduled and emergency procedures within 60 minutes of being called.

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²³ Generally, the minimum safe number of perfusion staff: defined as $N + 1$, where N equals the number of operating/procedure rooms **requiring cardiopulmonary bypass** at any given time at a single site. (Ref: UK Code of Practice https://assets.website-files.com/5da4ad68b9d5374c5a54c71d/5da742c4b9d497537544e0b7_SCPS-%20CODE%20OF%20PRACTICE%20-%202019.pdf; accessed **March 6, 2021**).

Example: 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.

Standard 16: Duty Hours

Standard 16.1: In order for the Perfusionist to ensure proper provision of care, he/she shall receive an adequate rest period between scheduled work hours.²⁴

Guideline 16.1: The Perfusionist should receive a minimum of 8 hours of rest period for every 16-hour consecutive work period.

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²⁴ 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
https://assets.website-files.com/5da4ad68b9d5374c5a54c71d/5da743ffa1b0aaa1cb7351e0_SCPS%20-%20Standards%20Of%20Practice%20-%202019.pdf (accessed March 6, 2021)

Standard 17: Quality Assurance and Improvement

Standard 17.1: The Perfusionist shall actively participate in both institutional and departmental quality assurance and improvement programs, **as well as encourage the use of safety reporting structures and incident reporting.**

Standard 17.2 The Perfusionist shall collect data concerning the conduct of perfusion via a clinical registry or database to advance quality and safety.^{25,26}

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²⁵ Warren CS, DeFoe GR, Groom RC, Pieroni JW, Groski CS, Morse CB, Connors EM, Lataille PJ, Ross CS, Likosky DS; Northern New England Cardiovascular Disease Study Group. Variation in arterial inflow temperature: a regional quality improvement project. J Extra Corpor Technol. 2011 Jun;43(2):58-63. PMID: 21848173; PMCID: PMC4680024.

²⁶ Baker RA, Newland RF, Fenton C, McDonald M, Willcox TW, Merry AF; Perfusion Downunder Collaboration. Developing a benchmarking process in perfusion: a report of the Perfusion Downunder Collaboration. J Extra Corpor Technol. 2012 Mar;44(1):26-33. PMID: 22730861; PMCID: PMC4557436.

Standard 18: Maintenance

- Standard 18.1:** The Perfusionist shall ensure that equipment used in the conduct of **extracorporeal support is properly maintained and functioning**
- Standard 18.2:** 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 18.3:** The organization shall follow a protocol for perfusion equipment failures.²⁷
- Standard 18.4:** Appropriate backup perfusion supplies shall be readily available.
- Standard 18.5:** The organization shall follow a protocol for acknowledging and addressing perfusion equipment notices (e.g., recalls, warnings, and advisories).

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²⁷ New CMS & Joint Commission Regulations on Medical Equipment Maintenance: Taking the Smart Approach to Compliance. ABM Healthcare Support Services. <https://info.abm.com/New-CMS-Joint-LP.html> (Accessed **March 6, 2021**)

Standard 19: Crisis Management

- Standard 19.1:** The perfusionist shall participate in a collaborative effort to implement an actionable crisis management plan for unforeseen circumstances that may prohibit the ability to perform standard duties.²⁸
- Guideline 19.1: Alternate vendors for vital equipment should be identified in order to address supply chain interruptions.
- Guideline 19.2: Alternate storage and staging areas should be identified in the event primary/routine areas are compromised.
- Guideline 19.3: Perfusionist should have a working knowledge of the infrastructure of the institution in order to identify operating room facilities that are suitable for extracorporeal support procedures when routine surgical suites are unavailable.
- Guideline 19.4: Clinical personnel should have a procedure for patient evacuation and potential support for patients committed to extracorporeal support while evacuations are in progress.
- Guideline 19.5: Clinical expertise and proper role assignment should be considered if Perfusion staff repurposing is required.

²⁸ Preparedness for Specific Types of Emergencies. Centers for Disease Control and Prevention (<https://emergency.cdc.gov/planning/>) (accessed March 6, 2021).

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.

2019 EACTS/EACTA/EBCP guidelines on cardiopulmonary bypass in adult cardiac surgery. Wahba A, Milojevic M, Boer C, De Somer FMJJ, Gudbjartsson T, van den Goor J, Jones TJ, Lomivorotov V, Merkle F, Ranucci M, Kunst G, Puis L; Eur J Cardiothorac Surg. 2019; 57: 210-251.

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. https://assets.website-files.com/5da4ad68b9d5374c5a54c71d/5da743ffa1b0aaa1cb7351e0_SCPS%20-%20Standards%20Of%20Practice%20-%202019.pdf (Accessed March 6, 2021)
- Codes of Practice Document. https://assets.website-files.com/5da4ad68b9d5374c5a54c71d/5da742c4b9d497537544e0b7_SCPS-%20CODE%20OF%20PRACTICE%20-%202019.pdf (Accessed March 6, 2021)

The Australian and New Zealand College of Perfusion.

- ANZCP Code of Ethical Practice. (<https://anzcp.org/wp-content/uploads/2020/06/ANZCP-IT-Code-of-Ethical-Practice.pdf> Accessed March 6, 2021)
- ANZCP Code of Professional Conduct. (<https://anzcp.org/wp-content/uploads/2020/06/ANZCP-IT-Code-of-Professional-Conduct.pdf> Accessed March 6, 2021)

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)
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.

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Appendix D: Blood gas, electrolyte and anticoagulation monitoring results

1. Blood gases

- a) pO₂
- b) pCO₂
- 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

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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 (6 th 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.

<u>Standard/Guideline</u>	<i>Regulations, Standards and Guidelines Resources</i>	<u>Section</u>
<u>Standard 1.1</u>	<i>AABB</i>	<i>1.3, 6.0, 6.1.1</i>
	<i>CAP-C</i>	<i>COM.10000</i>
	<i>CAP-G</i>	<i>GEN.20374, GEN.20375</i>
	<i>CMS-H</i>	<i>§482.11</i>
	<i>HFAP</i>	<i>30.00.09</i>
	<i>NIAHO</i>	<i>QM.1_SR.1a(2); QM.3; GB.1_SR.1a; SS.1</i>
	<i>ISO 9001</i>	<i>4.1; 4.2; 4.2.1; 4.2.2; 5.1</i>
	<i>TJC-HAP</i>	<i>LD.04.01.07; LD.04.01.07_EP2; LD.04.04.07_EP1-EP3; NS.02.02.01_EP3; NS.02.03.01</i>
	<i>TJC-L</i>	<i>DC.01.01.01_EP1-EP3; DC.02.02.01_EP1-EP4</i>
Standard 1.2 • <u>Dot point 1</u>	<i>AABB</i>	<i>1.1.1; 1.3; 1.4; 6.0; 6.1 (6.1.1, 6.1.3)</i>
	<i>CAP-C</i>	<i>COM.10000; COM.10200</i>
	<i>CAP-G</i>	<i>GEN.20375</i>
	<i>CIHQ</i>	<i>GL-4</i>
	<i>CMS – L</i>	<i>§493.1200 (a-c)</i>
	<i>COLA</i>	<i>ORG 11 E; ORG 12 R; LDR 3 E; LDR 5 E</i>
	<i>HFAP</i>	<i>30.00.09</i>
	<i>NIAHO</i>	<i>NS.2_SR.3</i>
	<i>ISO 9001</i>	<i>4.2.3</i>
	<i>TJC-HAP</i>	<i>LD.04.01.07_EP1; LD.04.04.07_EP4; NR.02.03.01_EP1-EP2;</i>
	<i>TJC-L</i>	<i>DC.02.01.01</i>

• <u>Dot point 2</u>	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
<u>Guideline 1.1</u>		
	AABB	1.3.1, 5.4.2.2.1
	CAP-C	COM.10000
	NIAHO	QM.5
	ISO-9001	1.2
<u>Standard 2.1</u>		
	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
<u>Standard 2.2</u>		
	AABB	2.1.3, 2.1.3.1

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

	<i>HFAP</i>	<i>01.00.04, 03.00.02, 03.01.06, 15.02.39, 16.00.04, 16.00.11, 18.00.06</i>
	<i>NIAHO</i>	<i>GB.1_SR.1c</i>
	<i>ISO 9001</i>	<i>6.2.1 (Note), 6.2.2</i>
	<i>TJC-HAP</i>	<i>HR.01.05.03_EP1, EP4</i>
	<i>TJC-L</i>	<i>HR.01.05.03_EP1, EP4-EP7</i>

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

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

<u>Dot point 4,</u> <u>Appendix D</u>	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
<u>Dot point 5</u>		
	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
<u>Guideline 4.1</u>	NIAHO	MR.5 (SR.2 – SR.5)
<u>Guideline 4.2</u>	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
<u>Guideline 4.3</u>	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
<u>Standard 5.1</u>	TJC-H	UP.01.01.01
<u>Standard 6</u>	NIAHO	SS.1; AS.1
	TJC-H	NPSG.06.01.01; LD.04.04.05
<u>Standard 6.1</u>	CIQH	QS-9
	TJC-H	NPSG.06.01.01
<u>Standard 6.2</u>	CIQH	QS-9
	TJC-H	NPSG.06.01.01
<u>Standard 6.3</u>	CIQH	QS-9
	TJC-H	NPSG.06.01.01
<u>Standard 6.4</u>	CIQH	QS-9
	TJC-H	NPSG.06.01.01
<u>Standard 6.7</u>	CIQH	QS-9
	TJC-H	NPSG.06.01.01
<u>Guideline 6.2</u>	CIQH	QS-9
	TJC-H	NPSG.06.01.01
<u>Standard 7</u>	CIHQ	AN-2 E
	HFAP	15.02.17
	NIAHO	AS.3_SR.2d(1)
	TJC-H	PC.01.02.01
<u>Standard 8</u>	TJC	NPSG.03.05.01
<u>Standard 8.1</u>	CIHQ	NS-3
	CMS-H	§482.23(b)(4)

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

	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
<u>Standard 11.2</u>	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
<u>Guideline 11.1</u>	AABB	1.3.1; 5.4.2.2.1
	CAP-C	COM.10000
	NIAHO	QM.5
	ISO-9001	1.2
<u>Standard 12.1</u>	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
<u>Standard 14.1</u>	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
<u>Guideline 14.1</u>	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
<u>Standard 17.1</u>	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
<u>Guideline 17.1</u>	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
<u>Guideline 17.2</u>	AABB	5.1.2.1; 5.1.2.2; 8.3; 9.0; 9.1; 9.2

	<i>CAP-G</i>	<i>GEN.16902; GEN.20316</i>
	<i>CIQH</i>	<i>QA-2 (D-E); QA-4; QA-5</i>
	<i>CMS-H</i>	<i>§482.21</i>
	<i>CMS-L</i>	<i>§493.1200; §493.1230; §493.1239</i>
	<i>COLA</i>	<i>QA 3 R; QA 4 R; QA 5 R</i>
	<i>HFAP</i>	<i>12.00.02; 12.00.04; 12.01.02</i>
	<i>NIAHO</i>	<i>QM.7; QM.8</i>
	<i>ISO 9001</i>	<i>8.2.2; 8.3; 8.4; 8.5.1; 8.5.2; 8.5.3</i>
	<i>TJC-H</i>	<i>PI.02.01.01; PI.03.01.01</i>
	<i>TJC-L</i>	<i>PI.03.01.01</i>
<u>Standard 18.1</u>	<i>AABB</i>	<i>3.5; 3.5.1; 3.5.1.1</i>
	<i>CIHQ</i>	<i>CE-8_A</i>
	<i>CMS-H</i>	<i>§482.26; §482.41; §482.53</i>
	<i>CMS-L</i>	<i>§493.1101; §493.1254</i>
	<i>HFAP</i>	<i>11.06.09; 11.06.10</i>
	<i>NIAHO</i>	<i>PE.1; PE.7</i>
	<i>TJC-H</i>	<i>EC.02.04.01; EC.02.04.03</i>
	<i>TJC-L</i>	<i>EC.02.04.01; EC.02.04.03</i>
<u>Standard 18.2</u>	<i>AABB</i>	<i>3.5; 3.5.1; 3.5.1.1</i>
	<i>CIHQ</i>	<i>CE-8 (B, D)</i>
	<i>CMS-H</i>	<i>§482.26; §482.41; §482.53</i>
	<i>CMS-L</i>	<i>§493.1101; §493.1254</i>
	<i>HFAP</i>	<i>11.06.09</i>
	<i>NIAHO</i>	<i>PE.1; PE.7_SR.6</i>
	<i>TJC-H</i>	<i>EC.02.04.01; EC.02.04.03</i>
	<i>TJC-L</i>	<i>EC.02.04.01; EC.02.04.03</i>
<u>Standard 18.3</u>	<i>CIQH</i>	<i>CE-8 (M, N)</i>
	<i>NIAHO</i>	<i>PE.7 (SR.4-SR.5)</i>

	<i>TJC-H</i>	<i>EC.02.04.01_EP9</i>
	<i>TJC-L</i>	<i>EC.02.04.01; EC.02.04.03</i>
<u>Standard 18.4</u>	<i>NIAHO</i>	<i>PE.7</i>
<u>Standard 18.5</u>	<i>HFAP</i>	<i>08.00.06; 25.00.00</i>
	<i>CMS-H</i>	<i>§482.25</i>
	<i>NIAHO</i>	<i>PE.1; PE.3; PE.7</i>
	<i>TJC-H</i>	<i>EC.02.02.01_EP11; MM.05.01.017</i>
	<i>TJC-L</i>	<i>EC.02.02.01_EP11</i>

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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 filter 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 ~~target~~ **achieved and results communicated**

- **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
- **WEANING/TERMINATION CHECKLIST**
 - ☐ ***Venous assist off / cardiectomy / venous reservoirs vented***
 - ☐ ***Shunt(s) closed***
 - ☐ ***Vent(s) clamed / removed***
 - ***All cannulas out***
 - ***Perfusion lines disconnected from patient***
- **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.

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