The American Society of ExtraCorporeal Technology (AmSECT) has created the following document based on clinical evidence and currently accepted perfusion practices. This document is meant to provide a framework to guide safe and effective cardiopulmonary bypass (CPB). AmSECT recommends that clinical teams implement the content of this document when developing institution-specific protocols for patients undergoing adult cardiac surgery utilizing CPB.

**Goal statement**

The goal of this project was to review and update AmSECT's current Essentials and Guidelines for Perfusion Practice. The AmSECT Board of Directors made this request in 2011 to the International Consortium for Evidence-Based Perfusion (ICEBP) committee.

**Overview of approach**

The members of the Executive Committee of the ICEBP independently evaluated and provided input regarding the current version of AmSECT's “Essentials and Guidelines” document. The proposed changes were shared with the perfusion community at AmSECT's International and Best Practices conferences in 2012. The revised document, now called “Standards and Guidelines” will serve as a useful guide for teams that wish to develop institution-specific standards and guidelines to improve the reliability, safety and effectiveness of CPB. AmSECT Standards and Guidelines will be reviewed, and updated as necessary, every two years, or as deemed appropriate by AmSECT's Board of Directors.

**Definitions**

**Standard:** Practices, technology and/or conduct of care that institutions shall meet in order to fulfil 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 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, anaesthesiologist, perfusionist, nurse and technicians.
Standard 1: -------- Development of Institutionally-based Protocols
Standard 2: -------- Qualification, Competency and Support Staff
Standard 3: -------- Perfusion Record
Standard 4: -------- Checklist Standard
Standard 5: -------- Communication
Standard 6: -------- Safety Devices
Standard 7: -------- Monitoring
Standard 8: -------- Anticoagulation
Standard 9: -------- Blood Management
Standard 10: ------- Gas Exchange
Standard 11: ------- Blood Flow
Standard 12: ------- Blood Pressure
Standard 13: ------- Quality Improvement
Standard 14: ------- Maintenance
Standard 15: ------- Duty Hours
**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.

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.

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\(^1\) 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/](http://www.abcp.org/)
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: A standardized process to educate, train, and annually evaluate perfusion staff should be developed and followed.

**Standard 3: Perfusion Record**

**Standard 3.1:** 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 record shall be maintained and stored according to institution policy for retaining patient medical records.

**Standard 3.2:** 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 3.1: The perfusion record should include open text (factual) commentary including supervising physician verbal orders pertinent to the CPB procedure.

Guideline 3.2: The perfusion record should include the signatures of the physician(s) providing oversight for the CPB procedure.

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Guideline 3.3: Raw data (eg. 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 4: Checklist**

**Standard 4.1:** The perfusionist shall use a checklist for each cardiopulmonary bypass (CPB) procedure\(^3\).

**Standard 4.2:** Checklists shall be included as part of the patient's permanent medical record.

Guideline 4.1: The perfusionist should use checklists in a read-verify manner where critical steps that should have been performed are confirmed.\(^4\) 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 4.2: 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 4.3: 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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**Standard 5: Communication**

**Standard 5.1:** 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.\(^5\)

Guideline 5.1: 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 5.2: Protocol driven communication (e.g. closed-loop), should be utilized to acknowledge verbal commands, verify the content, and reduce ambiguity.\(^7\)\(^8\)\(^9\)

Guideline 5.3: The primary perfusionist should participate in the post-procedure debrief with the surgical team.

**Standard 6: Safety Devices**

**Standard 6.1:** Pressure monitoring of the arterial line, cardioplegia delivery systems and venous reservoir (when augmented venous drainage is utilised), 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


\(^6\) ST-59 Statement on use of cell phones in the operating room by the American College of Surgeons, http://www.facs.org/fellows_info/statements/st-59.html


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**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.

- At least one method to prevent retrograde flow shall be employed for systems utilizing centrifugal pumps for systemic circulation. 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 scavange 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.

Standard 7: Monitoring

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.

\[^{10}\text{To be performed in conjunction with Standard 3.}\]

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**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 (H₂O temperature)

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

**Standard 7.7:** Hematocrit (or hemoglobin) shall be monitored continually during CPB.

**Standard 7.8:** Oxygen fraction and gas flow rates shall be monitored continually during CPB (Appendix D).

**Standard 7.9:** The percentage of venous line occlusion of the venous occluder shall be monitored continually during CPB.

**Standard 7.10:** Venous oxygen saturation shall be monitored continually during CPB.

**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 and/ or
- Pulmonary artery blood pressure

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

**Guideline 7.5:** Cerebral oximetry should be used during CPB.

**Guideline 7.6:** Arterial blood flow should be monitored continually at a point in the CPB circuit where it accurately reflects the flow delivered to the patient during CPB (e.g. distal to intra-circuit shunts).
**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: Additional doses of heparin during CPB should be determined by using an ACT and/or Heparin/Protamine titration.  

Guideline 8.5: Heparin reversal should be confirmed by ACT and/or heparin/protamine titration.

**Standard 9: Blood Management**

**Standard 9.1:** The Perfusionist shall participate in efforts to minimize hemodilution and avoid unnecessary blood transfusions.

**Standard 9.2:** The Perfusionist shall minimize the cardiopulmonary bypass (CPB) circuit size to reduce prime volume.

**Standard 9.3:** The perfusionist shall calculate and communicate to the surgical team prior to initiating CPB, a patient's predicted post-dilutional haemoglobin or hematocrit.

Guideline 9.1: Blood management efforts should include the following:

- Participate in pre-operative briefings (discussions) with the surgical care team (Standard 5.1) regarding transfusion strategies and target hematocrit values.
- Participation in a multidisciplinary blood management team.
- Minimize hemodilution by:
  - Matching the size of the CPB circuit to the size of the patient.
  - Autologous priming of CPB circuit, including retrograde arterial and venous antegrade priming.
  - Biocompatible coating on the surface of all CPB components.

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11 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 Ib, Level of evidence B). Ferraris et al 2011

• Perioperative blood cell recovery and reinfusion after being appropriately processed.
• CPB circuit blood salvage at the end of the procedure

Guideline 9.2: 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
  • Thromboelastography/Thromboelastometry
  • Platelet count
  • Platelet function analysis

**Standard 10: Gas Exchange**

**Standard 10.1:** 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 and metabolic demand

**Standard 10.2:** Devices used to measure gas exchange shall be calibrated according to the manufacturer’s instructions for use.

**Standard 10.3:** Blood gas analysis shall be performed and recorded according to protocol.

Guideline 10.1: Point-of-Care testing should be considered to provide accurate and timely information for blood gas analysis

Guideline 10.2: Oxygen delivery and consumption calculations should be utilised to evaluate and optimize gas exchange

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- 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
SaO2 = arterial oxygen saturation
PaO2 = partial pressure of oxygen in arterial blood
SvO2 = venous oxygen saturation
PvO2 = partial pressure of oxygen in venous blood

**Standard 11: Blood Flow**

**Standard 11.1:** Target blood flow rates shall be determined prior to cardiopulmonary bypass (CPB) according to protocol.\(^{15}\)

**Standard 11.2:** The perfusionist shall work closely with the surgical care team to maintain targeted blood flow rate during CPB.

Guideline 11.1: Variance from intended and targeted blood flow should be communicated to the physician-in-charge.

Guideline 11.2: Appropriate blood flow rate should be determined by evaluation of:
- Acid base balance
  - Base excess
- Anesthetic level
- Arterial blood pressure
- Cerebral oximetry
- Lactate burden

\(^{15}\)Body Surface Area*Cardiac Index = Calculated Blood Flow Rate, where body surface area in square meters = square root of (height*weight/3600), using height in cm and weight in kg.
- Oxygen delivery and consumption (refer to Guideline 10.2 for formulae)
  - Venous pO₂
  - Arterial pO₂
  - Hemoglobin concentration
  - Arterial oxygen saturation
- Systemic vascular resistance (SVR)
- Temperature
- Venous oxygen saturation

**Standard 12: Blood Pressure**

**Standard 12.1:** 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.\(^\text{16}\)

**Standard 12.2:** The perfusionist shall work closely with the surgical care team to maintain blood pressure according to protocol during CPB.

Guideline 12.1: 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.

**Standard 13: Quality Assurance and Improvement**

**Standard 13.1:** The perfusionist shall actively participate in both institutional and departmental quality assurance and improvement programs.

Guideline 13.1: The perfusionist should collect data concerning the conduct of perfusion via a clinical registry or database.

\(^\text{16}\) 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.
Guideline 13.2: The Perfusionist should use such data for quality assurance, and improvement projects.\textsuperscript{17,18}

\textbf{Standard 14: Maintenance}

\textbf{Standard 14.1:} 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

\textbf{Standard 14.2:} Preventive maintenance on perfusion equipment shall be performed and documented on a regularly scheduled basis by the perfusion team and/or appropriately trained and qualified biomedical engineering staff. Any or all of the following may determine the interval of such maintenance:

- Manufacturer recommendations
- External accrediting agency guidelines
- Institutional requirements


\textsuperscript{18} Baker RA, Newland RF, Fenton C, McDonald M, Wilcox TW, Merry AF. J Extra Corpor Technol 2012: 44(1), 26-33
**Standard 14.3:** The organization shall have a written procedure for perfusion equipment failures\(^{19}\).

**Standard 14.4:** Appropriate backup perfusion supplies shall be readily available.

**Standard 15: Duty Hours**

**Standard 15.1:** In order for the perfusionist to ensure proper provision of care, he/she must receive an adequate rest period between scheduled work hours\(^{20}\).

**Guideline 15.1:** The Perfusionist should receive a minimum of 8 hours of rest period for every 16-hour consecutive work period\(^{21}\).

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\(^{21}\) Accreditation Council for Graduate Medical Education (ACGME) policies for Residents [http://www.acgme.org/acgmeweb/GraduateMedicalEducation/DutyHours.aspx](http://www.acgme.org/acgmeweb/GraduateMedicalEducation/DutyHours.aspx)
**Relevant Publications**


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) Names
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 are often 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 Cannulae
    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
   b. 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
    i. Solution (ratio)
    ii. Route
    iii. Flow
iv. Pressure
v. Temperature
vi. 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\textsubscript{2}
   b. pCO\textsubscript{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