



Recommendations

For Standards of

Monitoring and Safety during

Cardiopulmonary Bypass

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Recommendations for Standards of Monitoring and Safety during Cardiopulmonary Bypass (CPB)

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This document is available on the following websites:

Society of Clinical Perfusion Scientists of Great Britain & Ireland

www.scps.org.uk

Association for Cardiothoracic Anaesthesia and Critical Care

www.acta.org.uk

Society for Cardiothoracic Surgery in Great Britain & Ireland

www.scts.org

Introduction

The aim of this document is to determine **standards of monitoring and safety** during CPB for adult and paediatric surgery. These standards are considered by the Society of Clinical Perfusion Scientists of Great Britain and Ireland, the Association for Cardiothoracic Anaesthesia and Critical Care and the Society for Cardiothoracic Surgery in Great Britain and Ireland to be the minimal monitoring required during CPB. This includes monitoring for the onset of and weaning from CPB, and for confirmation of anticoagulation and ventilation of the lungs.

These standards are for use in conjunction with the Society of Clinical Perfusion Scientists of Great Britain and Ireland Standards of Practice document¹ and local protocols. Sources of reference include publications from the Society of Clinical Perfusion Scientists of Great Britain and Ireland¹, the Association of Anaesthetists of Great Britain and Ireland², the American Society of Extra-Corporeal Technology³ and the DH document – Guide to Good Practice in Clinical Perfusion (GGPCP)⁴.

(Within this document “on site facility” is defined as on the hospital site, “near patient facility” is defined as within or in close proximity to the cardiac theatre).

All centres undertaking cardiac surgery involving CPB should plan to institute these standards by 6 months from the date of publication.

The safe conduct of CPB is the joint responsibility of surgeons, anaesthetists and clinical perfusionists and requires a high level of communication between the team members. Whilst it is considered best practice during the conduct of CPB for a Consultant Cardiac Surgeon and Anaesthetist to be present in the operating room at all times during cardiopulmonary bypass, it is recognised that there are circumstances where this may not be essential. However, the safety

of CPB remains the primary responsibility of the perfusionist who must be present at all times. These situations should be managed using locally agreed clinical governance guidelines and protocols should be in place to ensure patient safety.

(Examples of such locally agreed guidelines, in relation to anaesthetic practice, can be found on the ACTA/ACACC website.)

Only an accredited clinical perfusionist registered with the College of Clinical Perfusion Scientists of Great Britain and Ireland must undertake or supervise the conduct of CPB^{1, 4, 5&6}. A named and accredited clinical perfusionist without the distraction of other clinical commitments, in close proximity and freely available must supervise a trainee undertaking a CPB¹.

This document should be used in conjunction with the World Health Organisation (WHO) surgical safety checklist or similar (e.g. Scottish Patient Safety Programme) and the Five Steps to Safer Surgery⁷ (or equivalent), and as guidance with these standards according to local protocols and policy.

This document is a review of the original guidelines—it will be reviewed regularly and may be revised or updated before the formal publication of a new edition. For the latest version, please visit the previously referred to websites.

General Recommendations

Adequate records of monitoring should be kept at all times and where a variable is monitored it should be regularly recorded. All units should have electronic acquisition and storage of this data, including the ability to produce a printout². Records should be stored electronically and retained in the patient's notes with this record containing all the variables monitored regularly during CPB.

All monitors and alarms used should be **calibrated and maintained regularly** according to the manufacturer's instruction and the recommended service schedule. All equipment must be checked before use.

During CPB, the electrocardiogram (ECG), intravascular pressures and core body temperature should be continuously displayed and clearly visible to the clinical perfusionist, surgeon and anaesthetist. (Ideally, three separate screens).

Patient Specific Directions (PSD) / Patient Group Directives (Wales) should be in place as agreed at local level and, where not forming a part of a CPB record, should be a document recording those directions for each individual patient and according to guidance in the GGPCP⁴.

All departments should be familiar with the GGPCP⁴ and this should be readily available for reference.

All departmental team members should receive adequate training on any device or equipment to be used with the Manufacturer's Instructions for Use (I.F.U.s) forming an integral part of that training and a record of training kept accordingly.

Monitoring of clinical parameters acquired directly from the patient

The following should be monitored and recorded continuously, (with local protocols dictating the frequency of recording):-

- **Electrocardiogram (ECG)**
- **Systemic arterial pressure**
- **Central venous pressure**
- **Core body temperature**
- **Urine output** should be monitored using a freely draining urinary catheter.
- **Pulse oximetry** should be continuously displayed when there is a spontaneous pulsatile circulation.
- **Expired carbon dioxide tension/concentration** should be continuously displayed when the lungs are being ventilated.
- The use of **Bispectral Index (BIS)** monitoring should be considered particularly in the presence and use of volatile Anaesthetic agents during CPB.

- The use of **Near InfraRed Spectroscopy (NIRS)** for Cerebral Oximetry monitoring should also be considered for certain procedures requiring CPB, e.g. Paediatric procedures, Aortic Root / Arch surgery, in patients with Carotid artery disease, procedures involving the use of retrograde arterial flow etc. (This list is not exhaustive and intended only as a guide).

N.B. It is accepted that special clinical circumstances (for example emergency surgery or failure to insert a urinary catheter) may, on some occasions, preclude complete monitoring.

Monitoring associated with the CPB circuit

The following should be monitored continuously and recorded accordingly:-

- **Oxygen saturation** of the blood in the venous return line.
- **Oxygen tension or saturation** of the blood in the arterial line.
- **Continuity of the fresh gas flow to the oxygenator** using an in-line flow meter or rotameter².
- **Oxygen concentration in the gas circuit to the oxygenator** using an oxygen analyser with alarms, sited after the oxygen blender and vaporiser if used ².
- **Blood flow rate** generated by the arterial pump.
- **Arterial line pressure** with consideration given to monitoring and recording the pressure pre-membrane pressure in addition to that of post-membrane.
- **Cardioplegia delivery line pressure & temperature** when Cardioplegia is delivered using the heart lung machine.

- **Temperature of the blood** in the venous & arterial limbs of the CPB circuit.
- **Temperature of water** in the heater/cooler system.
- **Fluid record**; all fluids, drugs and blood products added to the extra corporeal circuit pre & peri-CPB should be checked as required and, in the absence of a separate PSD, recorded on the perfusion chart and signed for accordingly⁷. Filtrate volume should be measured and recorded when a Haemofilter/ concentrator are being used.
- **Continuous “in line” monitoring screens** (e.g. for Haemoglobin / Hct, arterial & venous O₂ saturation and / or tension, CO₂ tension etc.) should be available and used when considered necessary.

The following measurements should be available at a near patient facility, (with local protocols dictating the frequency of recording):-

- **Anticoagulation** should be confirmed by an acceptable method e.g. Activated Clotting Time (ACT), which should be measured after heparinisation and before CPB and should be measured at regular intervals during CPB to ensure adequate anticoagulation.

Other parameters that should be measured are:-

- **Blood gases**

- **Red cell concentration** (Haemoglobin or Haematocrit).
- **Potassium**
- **Glucose**
- **Lactate**

Consideration should be given to measuring the following throughout the operative course via a near patient facility:-

- Heparin Dose Titration and levels during CPB.
- Platelet Function.
- Patient Coagulation Profiles (e.g. TEG).

The following measurements should also be available at an on site facility (if not available as above):-

- **Clotting studies**
- **Calcium**

Safety devices

Local protocols for the conduct of cardiopulmonary bypass should be formulated by all hospitals undertaking cardiac surgery using cardiopulmonary bypass.

The following are considered minimum safety standards:-

- **Power failure alarm** with a **battery powered back-up unit** for the cardiopulmonary bypass machine.
- Battery powered **Torch** sited near to the bypass machine.
- **Bubble detector** on the arterial line of a roller and centrifugal pump cardiopulmonary bypass circuit with an **alarmed automatic pump cut out facility**.
- A Bubble detector for use at an appropriate point in the Cardioplegia circuit with **alarmed automatic pump cut out facility** should be used if available.
- **Level sensor** on a hard shell venous reservoir system in the cardiopulmonary bypass circuit with an **alarmed automatic pump cut out facility**.
- **Retrograde Flow Alarm** and/or an **occlusion device** is essential when using a Centrifugal Pump as a means to prevent retrograde arterial blood flow.
- **Anaesthetic gas-scavenging apparatus** whenever volatile agents are used in the cardiopulmonary bypass circuit⁸.

- **Out of range temperature alarm** on the arterial limb of the CPB circuit.
- **Overpressure alarm** on the arterial limb of the CPB circuit with **automatic pump cut out/ flow reduction facility**.
- **Overpressure alarm** on the post pump aspect of the Cardioplegia circuit with **automatic pump cut out/ flow reduction facility**.
- The Cardioplegia circuit should be slaved to the main CPB circuit to ensure that the Cardioplegia flow does not exceed the blood flow to the patient in the event of an alarm condition in the main CPB circuit.
- **Handcranks** must be instantly available in the event of power supply issues or pump malfunction.

Additional Safety Guidance:-

- **Appropriate staffing levels** should be in place in line with the SCPS Code of Practice^{4, 9&10} i.e. **N+1** where N equals the number of operating theatres in use at any given time on a single site.
- **Suckers and vents** must be checked by the Clinical Perfusionist to confirm correct function and position to aspirate blood and air away from the heart or surgical site. Local protocol must include a compulsory occlusion method along with standard directional confirmation of all pumps. This must be recorded as double checked via a prebypass checklist and confirmed by a circulating / **N+1** Clinical Perfusionist. One way pressure relief valve connectors and/or the method commonly known as "wet

testing" may also be used in conjunction with checks recorded in line with local policy.

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Date of next Review: - August 2018 or earlier as deemed necessary.