TECHNICAL SPECIFICATION

ISO/TS 23810

Third edition
2018-07

Cardiovascular implants and artificial organs — Checklists for use of extracorporeal circulation equipment

Implants cardiovasculaires et organes artificiels — Listes de contrôle pour l'équipement de circulation extracorporelle

Reference number
ISO/TS 23810:2018(E)

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Published in Switzerland

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*.

This third edition cancels and replaces the second edition (ISO/TS 23810:2012), which has been technically revised.

Introduction

This document has been published as a Technical Specification instead of an International Standard for provisional application, so that individuals and/or professional groups who operate extracorporeal circulation (ECC) equipment (e.g. perfusionists) may gather information and experience of its use in practice. It can be used as a checklist, or a reasonable equivalent, before initiating extracorporeal circulation, which users are encouraged to adapt to accommodate differences in circuit design or variations in institutional clinical practice. It is intended to be used by healthcare facilities to create a checklist appropriate to the particular needs of their institution. While this checklist is intended to be comprehensive for many types of equipment used for ECC, inclusion of specific checklist items does not necessarily mandate their use.

The purpose of this document is to provide generic guidelines for the safe use of ECC equipment. Errors and omissions in the setup of ECC equipment have the potential to compromise the equipment's intended functionality. In some cases, compromised functionality may result in severe injury to, or the death of, the patient supported by ECC. Completing checklists before, during, and after a patient is placed on ECC support and also for post-operative management is an aid to reducing errors and to ensuring proper operation. Both users and patients can benefit from the use of such checklists. The manufacturer can also receive assurance that the product and/or equipment are being used according to the purposes for which it was designed and in accordance with the instructions for use.

The development of this document has been made possible thanks to the efforts of professional groups (see the Bibliography) in developing similar checklists and provides for their wider dissemination and recognition.

Extracorporeal circulation technology has been used clinically in a variety of concepts for more than 50 years and the equipment, techniques, and applications continue to evolve. While much technological advancement in devices and techniques have occurred during this time, the fundamental purpose of ECC remains unchanged. Thus, generic checklists are applicable to several modalities of ECC (see Scope) and may be customized by clinicians for specific use depending on institutional or physician-mandated applications. The acceptance into general practice of any guideline is most reasonably ensured if those who must use such guidelines can reach consensus agreement on the key issues to be covered in a checklist. The benefits to be gained assume a reduction in errors when a variety of ECC equipment is used clinically.

Finally, this document fills an important niche in the improvement of patient safety, since no regulation or standard exists in the area of preoperative checklists for ECC equipment.

Cardiovascular implants and artificial organs — Checklists for use of extracorporeal circulation equipment

1 Scope

This document covers the activities performed by perfusionists before, during, and after extracorporeal circulation.

Clause 4 covers the perfusionists' actions during preoperative extracorporeal circulation (ECC) equipment setup prior to cardiopulmonary bypass (CPB), extracorporeal membrane oxygenation (ECMO), cardiopulmonary support (CPS), left or right heart bypass (LHB/RHB) or venovenous (VV) extracorporeal support for liver transplantation. Its requirements can serve as a checklist for verifying that the equipment, devices or systems have been set up correctly. The sequence of use of checklist items listed below can vary depending on customary institutional use or individual user preference. There are also four additional checklists for different phases of ECC (see Clause 5, Termination; Clause 6, Post-extracorporeal circulation; Clause 7, Emergent reinstitution of extracorporeal circulation; and Clause 8, Peri-procedural).

2 Normative references

There are no normative references in this document.

3 Terms and definitions

No terms and definitions are listed in this document.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at https://www.iso.org/obp

4 Preoperative requirements

4.1 Patient information

4.1.1 Rationale

To minimize the risk of misidentifying the patient and the proposed procedure, which could lead to use of inappropriate equipment and/or an inappropriate procedure, the correct patient for the correct procedure should be confirmed before the procedure begins. A time-out in which the patient's name with other identifying information and the proposed procedure is announced and acknowledged by all team members present is an important method for addressing this issue. Users should read relevant portions of the patient's medical record to confirm the patient's history that could potentially affect the safe conduct of extracorporeal circulation. Blood products may be needed urgently during extracorporeal circulation, so the availability of correctly typed and crossed blood matched for administration to the intended patient should be confirmed. For patients with specific blood product restrictions and limitation of usage an alternative protocol shall be reviewed and confirmed.

4.1.2 Patient interview

Interview the patient except in the case of a patient condition that would prevent direct communication and/or review the patient's records, as per institutional protocol.

4.1.3 Patient identity

4.1.3.1 Confirm the patient's identity by matching the patient's hand band with information in the patient chart.

4.1.3.2 Cross check the patient's identification with a clinical team member assigned to the case.

4.1.3.3 Other methods for patient identification such as asking the patient his or her name and date of birth may be used per institutional protocol.

4.1.4 Medical record number

Crosscheck the hospital identity number for the patient with the patient's medical record and record it on any chart-work associated with the procedure.

4.1.5 Allergies

4.1.5.1 Confirm from the patient's medical record whether there are any known or reported allergies and record such information on any chart-work associated with the procedure.

4.1.5.2 Confirm the patient's allergy status with a clinical team member assigned to the case.

4.1.6 Blood bank numbers

4.1.6.1 Confirm the number of units of blood available.

4.1.6.2 Match the identity of all designated blood bank products to the patient and double-check before administering to the patient or into the extracorporeal circuit.

4.1.7 Blood type and antibodies

Confirm the patient's blood type and possible antibody status by review of laboratory reports in the patient's chart before the procedure.

4.1.8 Chart

Review the patient's medical chart before the procedure to determine vital statistics (e.g. height, weight, body surface area, age, gender) or any other relevant information that could affect the performance of extracorporeal circulation (e.g. haemoglobin/haematocrit, predicted haemoglobin/haematocrit during ECC and any other relevant laboratory values or medical history/risk factors).

4.1.9 Procedure

4.1.9.1 Review the patient's medical chart before the procedure to determine the intended medical indication or surgical procedure.

4.1.9.2 Confirm the procedure by implementing a time-out with the clinical team.

4.2 Equipment and Instructions for Use

4.2.1 Rationale

The choice of equipment and ancillary devices to be used for extracorporeal circulation shall be appropriate to the patient and proposed procedure for safe conduct of ECC. Users shall have read and understood the most current manufacturers' instructions for use to guide appropriate management of extracorporeal circulation.

4.2.2 Equipment

Confirm the equipment chosen for use (disposable and reusable) is of the appropriate size and model for the intended procedure and patient size.

4.2.3 Instructions for Use

Confirm the user has read and understood the most current manufacturers' instructions for use and is aware of any modifications/changes in order for the products to be operated and used safely before the products are used, including before the preparation period.

4.3 Sterility/cleanliness

4.3.1 Rationale

All disposable equipment (e.g. oxygenators, reservoirs, tubing, cardioplegia delivery systems, monitoring lines, and transducers) that will come into contact with the patient's blood shall be sterile to avoid infection. The surfaces of all non-disposable equipment (e.g. pump console, poles, trays, tubing clamps, and ancillary systems such as cell salvage and self-standing cooler/heater units) should be blood-free and body fluid-free before assembly of disposable equipment to minimize the risk of transmission of blood-borne pathogens to the patient or user. Self-standing cooler/heater units using water or ice shall be clean to reduce the risk of patient infection in the event there is a water-to-blood leak or transmission of circulating water onto the sterile field.

4.3.2 Component package integrity/expiration dates

Visually inspect all component packaging and labelling prior to assembly to verify sterility and expiration date.

4.3.3 Serial/lot numbers

Record the serial and/or lot numbers of components (e.g. oxygenator, reservoir, circuit tubing, cardioplegia system), as well as the identification of the pump consoles.

4.3.4 Equipment

Confirm that reusable equipment is blood-free, body fluid-free, and clean prior to assembly, which may include regular cleaning with an appropriate disinfectant per institutional protocol.

4.3.5 Heat exchanger(s)

4.3.5.1 For the water phases of all heat exchanger components, connect water source(s) with circulating water and visually verify that there is no water leakage into the blood pathway(s) prior to adding fluid priming volume.

4.3.5.2 Pressurized air or water without decay may be used as a method to verify heat exchanger water phase integrity.

4.3.6 Maintenance

Confirm that all equipment has been maintained according to manufacturers' recommendations and institutional regulation.

4.4 Pumps

4.4.1 Rationale

Blood pumps used for circulatory support, cardioplegia delivery, or aspiration of blood/air from the surgical site shall be in proper working order with backup (electrical and/or mechanical) to avoid the risk of inadequate delivery of extracorporeal circulation. Accurate displays of blood flow (e.g. read-outs or flow meters) are important to avoid either hypo- or hyper-perfusion.

NOTE Pumps refers to all pumps, including arterial, and those used with subsystems such as vents, cardioplegia and suckers.

4.4.2 Electrical

4.4.2.1 Power cord connections

4.4.2.1.1 Confirm that all electrical power cords are securely connected to the appropriate power source(s).

4.4.2.1.2 Route all electrical power cords so as to minimize the risk of inadvertent disconnection from the power source.

4.4.2.1.3 Confirm that no electrical power cords compromise patient electrical isolation.

4.4.3 Batteries

Confirm that all battery-powered devices are sufficiently charged and that each device is functional by temporarily disconnecting the AC power source to verify battery operation.

4.4.4 Roller pumps

Confirm that each roller rotates freely by manually rotating it before placing tubing in the roller pump housing, to verify freedom of motion and absence of jammed bearings.

4.4.4.1 Speed controls

4.4.4.1.1 Turn the speed controls of each pump to high speed and return to low speed while confirming proper response, including correct direction of pump rotation.

4.4.4.1.2 If a reverse mode exists, check each pump's reverse mode for functionality by turning the switch to the reverse mode and verifying operational effectiveness. Confirm correct roller pump direction before use.

4.4.4.1.3 Re-confirm speed control functionality after tubing has been placed in the roller pump housing.

4.4.4.2 Pump head rotation

4.4.4.2.1 Tubing should be wet/primed before placing it in the roller pump housing.

4.4.4.2.2 Confirm that all pumps rotate effectively with tubing in place and primed with fluid.

4.4.4.3 Occlusion(s)

Set the degree of occlusion of all roller pumps properly, to reasonably ensure effective displacement, low trauma and low spallation.

4.4.4.4 Flow probe(s)

Confirm that flow probes, if used, are installed in the tubing in the correct direction, and are calibrated and verified to be working properly.

4.4.4.5 Flow rate indicator

Confirm that flow rate indicators are appropriate for the patient's size and conform to the tubing size being used.

NOTE The flow indicator when using multiple sizes of tubing in the roller pump that has a multi-tube holder (e.g. cardioplegia) cannot be ensured except during the time of actual delivery by observation.

4.4.4.6 Tubing holders

Confirm tubing holders on the inlet and outlet sides of the roller pump housing are secure so as to prevent tubing slippage or movement within the roller pump head during operation.

4.4.4.7 Servo-regulated connections

Confirm that all electrical or mechanical connections controlling pumps are securely connected to the correct terminals and are tested to be functional.

4.4.5 Centrifugal pumps

4.4.5.1 Confirm that the mechanical position of the centrifugal pump is secure for proper electromagnetic field alignment/coupling and mounting on the pump console.

4.4.5.2 Confirm that flow probes are installed in the tubing in the correct direction, and are calibrated and verified to be working properly.

4.4.5.3 Confirm the retrograde flow alarm is tested to be functional.

4.4.5.4 Confirm the one-way valve, if used, is connected correctly and secure.

4.5 Cardioplegia

4.5.1 Rationale

Cardioplegia during cardiopulmonary bypass provides a still operative site for the surgical procedure while protecting the heart during ischaemic arrest. It is important that the solutions used, method of delivery, integrity of the system, and delivery temperature(s) are confirmed before use and during delivery for safe myocardial protection.

4.5.2 Solutions

Confirm that the solution(s) to be used for myocardial preservation are of the proper composition, temperature and within expiry date.

4.5.3 Method of delivery

Confirm the method of delivery (e.g. antegrade, retrograde, blood-to-solution ratio) prior to use.

4.5.4 Heat exchanger leaks

Test the cardioplegia delivery system heat exchanger water compartment, if used, before priming and confirm that it is leak-free by connecting water source(s) with circulating water and visually verify there is no water leakage into the blood/fluid pathway(s) prior to adding fluid priming volume.

4.5.5 Temperature control

Confirm water from cooler/heater flows freely through the heat exchanger of the cardioplegia delivery system.

4.5.6 Bubble removal

Confirm that the cardioplegia delivery system is free of visible bubbles after fluid priming.

4.5.7 Leak-free

Confirm that the cardioplegia delivery system does not leak with clinically relevant pressures.

4.6 Medical gas supply

4.6.1 Rationale

Uninterrupted and adequate gas exchange and accuracy of gas mixtures shall be ensured for meeting the metabolic needs of the patient during extracorporeal circulation to avoid patient injury.

4.6.2 Circuit gas line(s) connection(s)

Confirm that all sources of gas supply to the circuit are secure and verify appropriate distal gas flow when the vaporizer, if used, is turned on.

4.6.3 Source(s) and connections of gas(es)

Confirm that all gas supply lines are connected to the appropriate sources and with correct pressure settings.

4.6.4 Flow meter/gas blender

4.6.4.1 Confirm the flow meter/gas blender is in calibration.

4.6.4.2 Test the gas flow meter and gas blender at clinical operating flow ranges.

4.6.4.3 Test the full oxygen concentration setting ranges from FiO_2 of 0,21 to 1,0.

4.6.5 Hoses

4.6.5.1 Confirm that all hoses and tubing used to deliver gas to the extracorporeal circuit are leak-free.

4.6.5.2 Confirm the moisture trap is functional.

4.6.5.3 Confirm the gas loss alarm is functional.

4.6.6 Gas exhaust

Confirm, both visually and tactilely, that the oxygenator gas exhaust pathways are unobstructed by other equipment or materials.

4.6.7 Inhalational gas scavenge line

4.6.7.1 Confirm that any device or tubing configuration connected to the oxygenator gas exhaust and intended to remove residual anaesthetic vapours is operational.

4.6.7.2 Confirm the gas scavenge system is not adversely affecting the accuracy of gas concentration reading systems.

4.6.8 Oxygen sensor

If using an in-line oxygen analyser in the gas delivery tubing, confirm that the oxygen concentration indicated by the in-line analyser matches the FiO_2 control dial setting on the blender.

4.6.9 Operating pressures for gas sources

Confirm the proper operational pressures for all gas sources.

4.6.10 Gas filter

4.6.10.1 Confirm the gas filter is intact and is inserted in the correct direction for flow before use.

4.6.10.2 Confirm the efficiency of the gas filter.

4.7 Vacuum supply

4.7.1 Rationale

Confirmation and appropriate maintenance of a vacuum source and alarms over the anticipated ranges is necessary for safe conduct of extracorporeal circulation to prevent inadequate negative pressure, which could lead to system malfunction and/or patient injury.

4.7.2 Vacuum line connections

Confirm that all sources of vacuum supply, if used, are securely connected to the circuit.

4.7.3 Vacuum source connections

Confirm that all vacuum supply lines are connected to the appropriate sources.

4.7.4 Vacuum source pressures

Confirm proper operational pressures for all vacuum sources.

4.8 Components

4.8.1 Rationale

Multiple components necessary for the safe conduct of extracorporeal circulation shall be mounted and secured properly, and those that carry fluids shall be primed and debubbled prior to use to avoid leaks and/or air embolism, which could injure the patient.

4.8.2 Connections/stopcocks/caps

Confirm that all tubing connections, stopcocks, sterile caps or accessories are securely attached to the appropriate components.

4.8.3 Tubing and shunts

Confirm that tubing or shunts intended to be clamped are securely clamped or closed.

4.8.4 Tubing direction

Manually trace that the direction of tubing for blood/fluid/gas flow is correct.

4.8.5 Tubing lengths and kinks

Confirm that all tubing is of appropriate lengths and kink-free.

4.8.6 One-way valve(s)

Confirm that all one-way valves are assembled in the correct direction.

4.8.7 Bubble removal

4.8.7.1 Confirm that all system components and tubing are free of visible bubbles after fluid priming.

4.8.7.2 A carbon dioxide flush may be used as an aid to debubbling; if this technique is employed, verify completion prior to immediate fluid priming.

4.8.8 Leaks

Confirm that no system component or tubing leaks fluid during fluid recirculation and pressurization.

4.8.9 Patency of arterial line/cannula

4.8.9.1 Confirm that the systemic flow tubing and cannula are in unrestricted continuity with the patient's arterial circulation.

4.8.9.2 Confirm that no bubbles are introduced into the system.

4.9 Safety mechanisms

4.9.1 Rationale

Components designed to ensure adequate function (e.g. detection of inadequate flow of blood or gases, air embolism, retrograde flow, or high pressure) of extracorporeal circulation are intended to automatically alert and/or alarm if patient risk is present. Other safety mechanisms employed should allow proper control during the conduct of extracorporeal circulation.

4.9.2 Alarms

4.9.2.1 Confirm that all alarms or alerts are properly connected and turned on and have been tested to be functioning appropriately according to the manufacturers' instructions for use.

4.9.2.2 Confirm audible warning devices are set to sound at appropriate levels according to institutional protocol.

4.9.3 Arterial filter/bubble trap

Confirm that the arterial filter or bubble trap in the systemic flow line is bubble-free after fluid priming.

4.9.4 Cardiotomy/hard-shell venous reservoir(s)

Confirm that all hard-shell reservoirs intended to be vented to atmosphere are functional.

4.9.5 Venous line occluder

Confirm that mechanical or electromechanical venous tubing occluders, if used, are calibrated and verified to be functioning.

4.9.6 Devices attached to console

Confirm that all components of the circuit are securely attached to holders and secured on the extracorporeal system console.

4.9.7 Arterial line occluder

Confirm that mechanical or electromechanical arterial line occluders, if used, are functioning.

4.9.8 Vent(s) and suctions

Confirm that vent(s) and suctions are aspirating fluid and not blowing air.

4.9.9 Level sensor for dynamic priming

Confirm dynamic reservoir level when recirculating through an unobstructed and closed arterio-venous loop at calculated flows to determine proper placement of level sensor.

4.10 Assisted venous return

4.10.1 Rationale

Pressure-relief valves (positive and negative) are necessary to avoid excessive pressures that can damage red blood cells, result in retrograde air embolism, or implosion or explosion of venous reservoirs. If a kinetic pump is used for assisted venous return it shall be confirmed to be inserted correctly, primed, debubbled, leak-free, and functional before starting extracorporeal circulation.

4.10.2 Positive pressure-relief valve

Confirm positive pressure relief valve(s) or display(s) (e.g. electronic pressure display or empty sterile fluid bag connected to reservoir port) either integral or attached to the hard-shell cardiotomy/venous reservoir is/are functioning.

4.10.3 Negative pressure-relief valve

Confirm negative pressure-relief valves, either integral or attached to the hard-shell cardiotomy/venous reservoir, are unobstructed and functional.

4.10.4 Vacuum regulator

Confirm that the device used for regulating the degree of vacuum within the hard-shell cardiotomy/venous reservoir is functional over appropriate ranges.

4.10.5 Kinetic-assisted venous drainage

4.10.5.1 Confirm the pump operational speed control and functionality.

4.10.5.2 Confirm the correct flow probe direction visually.

4.10.5.3 Confirm that the pump and bypass lines are debubbled and leak-free, and all bypass lines are clamped securely.

4.11 Monitoring

4.11.1 Rationale

Probes and sensors are necessary to ensure proper operation and assessment of extracorporeal circulation.

4.11.2 Temperature probes

Confirm that all temperature probes (patient and circuit including water sources) are in place and functioning.

4.11.3 Pressure transducers/monitors

Confirm that all pressure transducers (patient and circuit) have been calibrated and are displayed on appropriate scales.

4.11.4 Flow probe(s)

Confirm that all flow probes have been calibrated and are functioning.

4.11.5 In-line sensor(s)

Confirm that all in-line sensors (e.g. blood/gas, chemistry, oxygen saturation, haemoglobin/haematocrit), if used, have been calibrated and are functioning.

4.12 Anticoagulation

4.12.1 Rationale

Periodic assessment of the patient's anticoagulation status is necessary to prevent coagulation within the circuit, possible thromboembolism to the patient's circulation, and/or device malfunction.

4.12.2 Monitoring devices

Confirm anticoagulation monitoring devices have been calibrated and are functioning.

4.12.3 Time and dose

Confirm the dose and time of administration of systemic anticoagulation.

4.12.4 Anticoagulation tested and reported

Test, document, and verbally report systemic anticoagulation.

4.13 Temperature control

4.13.1 Rationale

A system for the maintenance of normothermia or the induction and reversal of hypothermia is a necessary adjunct for protection of the patient and organ systems during extracorporeal circulation.

4.13.2 Water source(s)

Confirm all heat exchangers that use water sources (e.g. oxygenator, cardioplegia) are connected and circulating water appropriately.

4.13.3 Temperature range(s)

Confirm that all water sources for circuit heat exchangers (e.g. oxygenator, cardioplegia) are functional over the full range of expected temperatures to be used.

Some recirculating water sources are set to not exceed 37 °C to 39 °C to avoid cerebral hyperthermia; if this safeguard is used, the maximum water temperature setting should be confirmed.

4.13.4 Water lines

Confirm that all heat exchanger water lines are unobstructed.

4.14 Supplies

4.14.1 Rationale

Equipment and supplies that will be used during the procedure and for possible component change-out shall be readily available to avoid patient injury due to potential time delays.

4.14.2 Tubing clamps

Confirm that an adequate number of appropriately sized tubing clamps have been counted and are readily available for the anticipated duration of the procedure.

4.14.3 Drugs

4.14.3.1 Confirm that all drugs that might be required to be administered into the circuit are readily available in adequate amounts.

4.14.3.2 If such drugs are pre-drawn into syringes, confirm that the syringes are clearly labelled with the drug name and concentration (e.g. mg/cc).

4.14.4 Solutions

Confirm that all solutions (e.g. crystalloid, cardioplegia) for a procedure are readily available in adequate amounts.

4.14.5 Blood products

Confirm that all blood products that might be required to be administered into the circuit are readily available in adequate amounts.

4.14.6 Sampling syringes/laboratory tubes and supplies

Confirm that syringes in appropriate sizes, laboratory sample tubes, and supplies (including ice, if required) are available for the number of anticipated uses.

4.14.7 Inhalational anaesthetic

4.14.7.1 Confirm that the correct anaesthetic vaporizer, if used, is in place in the gas delivery line.

4.14.7.2 Confirm that the anaesthetic vaporizer, if used, is operational and contains the appropriate anaesthetic in adequate amounts.

4.15 Backup

4.15.1 Rationale

Equipment and supplies shall be readily available in the event of pump malfunction, device failure or inoperability, or loss of lighting, power, or gas supply to ensure uninterrupted maintenance of adequate extracorporeal circulation.

4.15.2 Hand cranks or uninterruptible power supply

Confirm that manual hand cranks and/or uninterruptible power supply used to operate systemic and/or other pumps are readily available and operational in the event that electrical power is interrupted.

4.15.3 Emergency lighting

Confirm that portable lighting (e.g. flashlight) is readily available and functional.

4.15.4 Backup oxygen tank with flow meter

Confirm that a functional secondary source of oxygen, with a flow meter for supplying the oxygenator, is readily available.

4.15.5 Duplicate circuit components and hardware

Confirm that replacement components (e.g. disposables such as oxygenator, arterial filter, reservoirs, tubing or connectors, and reusables such as brackets, modular pump controls or flow meters) are readily available in the event of failure or loss of functionality of any system component.

4.15.6 Ice

Confirm a readily available source of ice for cooler/heaters that require the use of ice to function effectively.

5 Weaning and termination

5.1 Rationale

The transition to normal patient circulation and physiology from extracorporeal circulation is a critical period, and precautions during weaning shall be ensured to provide a safe transition.

5.2 Inhalational anaesthetic

Confirm discontinuation of delivery of inhalational anaesthetic, if used.