TECHNICAL SPECIFICATION

ISO/TS 23810

First edition
2006-07-15

Cardiovascular implants and artificial organs — Checklist for preoperative extracorporeal circulation equipment setup

Implants cardiovasculaires et organes artificiels — Liste de contrôle pour l'installation d'équipement de circulation extracorporelle préopératoire

Reference number
ISO/TS 23810:2006(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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of normative document:

— an ISO Publicly Available Specification (ISO/PAS) represents an agreement between technical experts in an ISO working group and is accepted for publication if it is approved by more than 50 % of the members of the parent committee casting a vote;

— an ISO Technical Specification (ISO/TS) represents an agreement between the members of a technical committee and is accepted for publication if it is approved by 2/3 of the members of the committee casting a vote.

An ISO/PAS or ISO/TS is reviewed after three years in order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn. If the ISO/PAS or ISO/TS is confirmed, it is reviewed again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.

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.

ISO/TS 23810 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*.

Introduction

This Technical Specification is proposed for provisional application so that individuals and/or professional groups who operate extracorporeal circulation equipment (i.e., perfusionists) may gather information and experience of its use in practice. This checklist, or a reasonable equivalent, should be used before initiating extracorporeal circulation. This checklist is a guideline that users are encouraged to modify to accommodate differences in circuit design or variations in institutional clinical practice. This document is intended to be used by healthcare facilities to create a checklist appropriate to the particular needs of their institution.

The purpose of this Technical Specification is to provide a generic guideline for safe use of extracorporeal circulation (ECC) equipment. Errors and omissions in the setup of ECC equipment have the potential to compromise the intended functionality of ECC equipment. In some cases, compromised functionality may result in severe injury or death of the patient supported by ECC. Completing a checklist before a patient is placed on ECC support is an aid intended to reduce errors and ensure proper pre-use setup of ECC. Both users and patients will be beneficiaries of ECC preoperative checklists. Manufacturers also receive assurance that their products and/or equipment are/is being used according to the purposes for which they are designed and in accordance with the Instructions for Use. This Technical Specification is feasible because of efforts to develop checklists by professional groups (see Clause 2). The evolution of these checklists into a Technical Specification by the International Organization for Standardization (ISO) provides wider dissemination and greater recognition of these recommendations. To assure optimal execution of this Technical Specification, input from perfusionist professional organizations play a key role. Extracorporeal circulation technology has been used clinically in a variety of concepts in the last 50 years and the equipment, techniques, and applications continue to evolve. While much technological advancement in devices and techniques has occurred during this time, the fundamental purpose of ECC remains unchanged. Thus, generic checklists are applicable to several modalities of ECC (see Clause 1) and may be customized by clinicians for specific use depending on institutional or physician-mandated applications. The acceptance into general practice of any recommended guideline is most reasonably assured if those who must put such guidelines into use can reach consensus agreement on 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 Technical Specification fills an important niche in improving patient safety since no regulation or standard exists in the area of preoperative checklists for ECC equipment.

Cardiovascular implants and artificial organs — Checklist for preoperative extracorporeal circulation equipment setup

1 Scope

This Technical Specification covers activities performed by perfusionists during equipment setup prior to cardiopulmonary bypass (CPB), extracorporeal membrane oxygenation (ECMO), cardiopulmonary support (CPS), left or right heart bypass (LHB, RHB) and venovenous (VV) extracorporeal support for liver transplantation. These checklist items should be considered for assuring verification that the equipment, devices or systems have been set up correctly. This checklist is comprehensive by design and may be modified by each institution in order to conform to specific procedures or institutional practice.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

American Academy of Cardiovascular Perfusion (Allentown, PA): Standards of practice. *Proc. Am. Acad. Cardiovasc. Perfusion* 1987, **8**, pp 272-274

American Society of Extra-Corporeal Technology (Reston, VA): Pre-bypass perfusion safety checklist. *Perfusion Life* 1990, **7**, pp 76-77

American Society of Extra-Corporeal Technology (Reston, VA): AmSECT Perfusion Checklist, updated by AmSECT Quality Committee, 2004

Anonymous: Anesthesia apparatus checkout recommendations, 1993, [Source unknown, but endorsed by American Society of Anesthesiology and U.S. Food and Drug Administration]

3 Requirements

3.1 Patient information

3.1.1 Patient interviewed

The patient shall be interviewed and/or the patient's records shall be reviewed, as per hospital protocol.

3.1.2 Patient identity confirmed

3.1.2.1 The patient identity shall be confirmed from the patient's chart and with the circulator nurse then verified.

3.1.2.2 Other methods for patient identification may be used per institutional protocol.

3.1.3 Medical record number transcribed and verified

The hospital identity number for the patient shall be crosschecked with the patient's medical record and shall be recorded on any chart work associated with the procedure.

3.1.4 Allergies verified

The patient's medical record shall be reviewed to determine whether the patient has any known or reported allergies and such information shall be recorded on any chart work associated with the procedure.

3.1.5 Blood bank number verified

3.1.5.1 The identity of all designated blood bank products shall be matched to the patient and double-checked before administration to the patient or into the extracorporeal circuit.

3.1.5.2 The number of units of blood available shall be confirmed.

3.1.6 Blood type, antibodies verified

The patient's blood type and possible antibody status shall be reviewed by reading laboratory reports in the patient's chart before the procedure.

3.1.7 Chart reviewed

The patient's medical chart shall be reviewed before the procedure to determine vital statistics (e.g., height, weight) or any other relevant information that could affect performance of extracorporeal circulation.

3.1.8 Procedure verified

3.1.8.1 The patient's medical chart shall be reviewed before the procedure to determine the intended medical indication or surgical procedure.

3.1.8.2 The procedure shall be confirmed with the surgeon.

3.1.9 Instructions for Use read

3.1.9.1 The user shall understand the manufacturer's Instructions for Use and be aware of any current modifications/changes in order to operate and use the products safely.

3.1.9.2 This shall be done before the products are used, including the preparation period.

3.2 Sterility/cleanliness

3.2.1 Components checked for package integrity/expiration dates

All component package and labelling shall be visually inspected prior to assembly to verify sterility.

3.2.2 Lot numbers

Lot numbers of components (oxygenator, reservoir, circuit) should be recorded as well as identification of the pump console.

3.2.3 Equipment clean

Re-usable equipment shall be verified to be blood-free and clean prior to assembly.

3.2.4 Heat exchanger(s) leak-tested

The water phases of all heat exchanger components shall have water source(s) connected with circulating water and visually verified to be free from water leakage into the blood pathway(s) prior to adding fluid priming volume.

NOTE Pressurized air without decay may be used as a method of verifying heat exchanger water phase integrity.

3.2.5 Maintenance

Verify that all equipment has been maintained according to manufacturer's recommendations.

3.3 Pumps [all pumps used with subsystems including vent(s), cardioplegia, and sucker(s)]

3.3.1 Electrical

3.3.1.1 Power cord(s) connection(s) secure

3.3.1.1.1 All electrical power cords shall be verified to be securely connected to the appropriate power source(s).

3.3.1.1.2 All electrical power cords shall be routed in such a manner as to minimize the risk of inadvertent disconnection from the power source.

3.3.1.1.3 All electrical power cords shall not compromise patient electrical isolation.

3.3.2 Batteries charged and functional

3.3.2.1 All battery-powered devices shall be verified to be charged and each device shall be verified to be functional.

3.3.2.2 All battery-powered devices shall be verified to be sufficiently charged and each device shall be verified to be functional by disconnecting the AC power source.

3.3.3 Speed controls operational

3.3.3.1 The pump(s) speed control(s) shall be turned to high speed and returned to low speed while confirming proper response, including correct direction of pump rotation.

3.3.3.2 The pump(s) reverse mode shall be checked for functionality by turning the switch to the reverse mode and verifying operational effectiveness. Correct roller pump direction shall be verified before use.

3.3.4 Rollers rotate freely

The ability of each roller to rotate freely shall be verified by manually rotating the rollers, before placing tubing in the roller pump housing, to confirm freedom of motion and absence of jammed bearings. Tubing shall be verified to be free of kinks or torsion.

3.3.5 Pump head rotation smooth and quiet

3.3.5.1 All pumps shall rotate smoothly after tubing has been installed.

3.3.5.2 All pumps shall rotate quietly when filled with fluid during recirculation.

3.3.6 Occlusion(s) set

The degree of occlusion of all roller pumps shall be set properly to assure effective displacement, low trauma, and low spallation.

3.3.7 Flow probe(s) in correct direction and calibrated

Flow probes shall be installed in the tubing in the correct direction, calibrated and verified to be working properly.

3.3.8 Flow rate indicator correct for patient and/or tubing size

Flow rate indicator(s) shall be appropriate for the patient's size and verified to conform to the tubing size being used.

3.3.9 Holders secure

Tubing holders on the inlet and outlet sides of the roller pump housing shall be secure to prevent tubing slippage or movement within the roller pump head.

3.3.10 Servo regulated connections tested

All electrical or mechanical connections controlling pumps shall be verified to be securely connected to the correct terminals and to be functional.

3.3.11 Coupling of centrifugal pump

The centrifugal pump shall be tested for secure mechanical position for proper magnetic field coupling and electrical mounting on the pump console.

3.3.12 Pump function

All pumps shall be tested and verified to be properly functional.

3.4 Cardioplegia

3.4.1 Solution(s) checked

Solutions used for myocardial preservation shall be verified to be of proper composition, temperature, and within expiry date.

3.4.2 Absence of water-to-blood leaks

The cardioplegia delivery system heat exchanger water compartment shall be tested before priming and verified to be leak-free.

3.4.3 System debubbled

The cardioplegia delivery system shall be free of air bubbles after fluid priming.

3.4.4 Leak-free after pressurization

The cardioplegia delivery system shall not leak under pressurization to clinically relevant pressures.

3.5 Gas supply

3.5.1 Gas line(s) connection(s) secure

All sources of gas supply to the circuit shall be verified to be secure.

3.5.2 Source and appropriate connections of gas(es) verified

All gas supply lines shall be verified to be connected to the appropriate sources.

3.5.3 Flow meter/gas blender functional

The gas flow meter and gas blender shall be tested at high and low gas flow settings and over the entire range of gas mixtures to be used.

3.5.4 Hoses leak-free

All hoses and tubing used to deliver gas to the extracorporeal circuit shall be verified to be leak-free.

3.5.5 Gas exhaust unobstructed

The oxygenator gas exhaust pathway(s) shall be verified visually and tactilely to be unobstructed by other equipment or materials.

3.5.6 Inhalational gas scavenge line functional

Any device or tubing configuration connected to the oxygenator gas exhaust and intended to remove residual anesthetic vapors shall be verified to be leak-free and operating properly.

3.5.7 Gas sensor

An inline oxygen analyser should be used in the gas delivery tubing to verify proper gas mixtures.

3.5.8 Operating pressures for gas sources

Proper operational pressures should be verified for all gas sources.

3.6 Components

3.6.1 Connections/stopcocks/caps secure

All tubing connections, stopcocks, sterile caps or accessories shall be verified to be securely attached to appropriate components.

3.6.2 Appropriate lines clamped and shunts closed

Tubing or shunts intended to be clamped shall be verified to be securely clamped.

3.6.3 Tubing direction traced and correct

All tubing shall be manually traced to verify correct direction of intended blood/fluid/gas flow.

3.6.4 No kinks noted

All tubing shall be verified to be kink-free.

3.6.5 One-way valve(s) in correct direction

All one-way valves shall be verified to be assembled in the correct direction.

3.6.6 System debubbled

All system components and tubing shall be free of visible bubbles. A carbon dioxide flush may be used as an aid to debubbling. If this technique is employed, completion shall be verified.

3.6.7 Leak-free after pressurization

All system components and tubing shall not leak fluid during fluid recirculation and pressurization.

3.6.8 Patency of arterial line/cannula verified

The systemic flow tubing shall be verified to be in unrestricted continuity with the patient's arterial circulation.

3.7 Safety mechanisms

3.7.1 Alarms operational, audible and engaged

3.7.1.1 All alarms or alerts shall be turned on and verified and tested to be functioning properly according to the manufacturer's Instructions for Use.

3.7.1.2 Audible warning devices shall be set to sound at appropriate levels according to institutional protocol.

3.7.2 Arterial filter/bubble trap debubbled

The arterial filter or bubble trap in the systemic flow line shall be bubble-free after fluid priming.

3.7.3 Cardiotomy/hard-shell venous reservoir(s) vented

All hard-shell reservoirs intended to be vented to atmosphere shall be verified to be properly vented to atmosphere.

3.7.4 Venous line occluder(s) calibrated and tested

Electromechanical venous tubing occluders shall be calibrated and verified to be functioning appropriately.

3.7.5 Devices securely attached to console

All components of the circuit shall be securely attached to holders and secured on the extracorporeal system console.

3.8 Assisted venous return

3.8.1 Cardiotomy positive pressure relief valve tested

Positive pressure relief valves either integral or attached to the hard-shell cardiotomy/venous reservoir shall be tested.

3.8.2 Negative pressure relief valve unobstructed

Negative pressure relief valves either integral or attached to the hard-shell cardiotomy/venous reservoir shall be tested.

3.8.3 Vacuum regulator tested

The device used for regulating the degree of vacuum within the hard-shell cardiotomy/venous reservoir shall be verified to be functional over appropriate ranges.

3.8.4 Pump head and bypass tubing operational when using kinetic-assisted venous drainage

3.8.4.1 The operational speed control and function shall be verified.

3.8.4.2 The correct flow probe direction shall be visually verified.

3.8.4.3 All bypass lines shall be verified to be debubbled and clamped.

3.9 Monitoring

3.9.1 Temperature probes in place

The location of all temperature probes (patient and circuit including water sources) shall be verified to be in place and functioning.

3.9.2 Pressure transducers/monitors calibrated and on proper scale(s)

All pressure transducers (patient and circuit) shall be verified to be calibrated, on appropriate scales, and functioning.

3.9.3 In-line sensor(s) calibrated

All in-line sensors (e.g., blood/gas, chemistry, oxygen saturation, haemoglobin/haematocrit) shall be calibrated and functioning.

3.9.4 Oxygen analyser calibrated

Oxygenator sweep gas analyser shall be calibrated at low and high (e.g., 21 % and 100 % oxygen) delivery values.

3.10 Anticoagulation

3.10.1 Heparin time and dose verified

The dose and time of administration of systemic heparin anticoagulation shall be confirmed.

3.10.2 Anticoagulation tested and reported

Systemic anticoagulation shall be confirmed, documented and verbally reported.

3.11 Temperature control

3.11.1 Water source(s) connected and functional

All water sources for circuit heat exchangers (e.g., oxygenator, cardioplegia) shall be connected and verified to be circulating water appropriately.

3.11.2 Temperature range(s) tested and functional

All water sources for circuit heat exchangers (e.g., oxygenator, cardioplegia) shall be verified to be functional over the full range of expected temperatures to be used.

3.11.3 Water lines unobstructed

All heat exchanger water lines (inlet and outlet) shall be verified to be unobstructed.

3.12 Supplies

3.12.1 Tubing clamps available

An adequate number of appropriately sized tubing clamps shall be counted and readily available to the operator for the anticipated duration of the case.

3.12.2 Drugs available and properly labelled

3.12.2.1 All drugs that might be required to be administered to the patient shall be readily available.

3.12.2.2 If such drugs are pre-drawn into syringes, the syringes shall be clearly labelled with the drug name and dosage.

3.12.3 Solutions available

All intravenous solutions (e.g., crystalloid, cardioplegia) that might be required to be administered to the patient shall be readily available.

3.12.4 Blood products available

All blood products that might be required to be administered to the patient shall be verified to be readily available.

3.12.5 Sampling syringes/laboratory tubes and supplies available

Syringes in appropriate sizes and laboratory sample tubes/supplies shall be available for the number of anticipated uses.

3.12.6 Inhalational anaesthetic correct

The anaesthetic vaporizer shall be verified to be correct.

3.12.7 Vaporizer operational and filled

The anaesthetic vaporizer shall be verified to be operational and filled with the appropriate anaesthetic.

3.13 Backup

3.13.1 Hand cranks available

Manual hand cranks to operate systemic and other pumps shall be readily available in the event electrical power is interrupted.

3.13.2 Emergency lighting available

Portable lighting (e.g., flashlight) shall be readily available and tested for proper function in the event room lighting is interrupted.