TECHNICAL SPECIFICATION

ISO/TS 23810

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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

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Contents

Page

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 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order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn.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again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.

This document is being issued in the Technical Specification series of publications (according to the ISO/IEC Directives, Part 1, 3.1.1.1) as a “prospective standard for provisional application” in the field of surgical implants because there is an urgent need for guidance on how standards in this field should be used to meet an identified need.

This document is not to be regarded as an “International Standard”. It is proposed for provisional application so that information and experience of its use in practice may be gathered. Comments on the content of this document should be sent to the ISO Central Secretariat.

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*.

This second edition cancels and replaces the first edition (ISO/TS 23810:2006), 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 (i.e. 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.

The purpose of this Technical Specification 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 a checklist before a patient is placed on ECC support is an aid to reducing errors and to ensuring proper pre-use setup. Both users and patients can benefit from the use of such a checklist. The manufacturer can also receive assurance that the product and/or equipment is being used according to the purposes for which it was designed and in accordance with the instructions for use.

The development of this Technical Specification 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.

ECC technology has been used clinically in a variety of concepts in the past 50 years and the equipment, techniques, and applications continue to evolve. While many technological advancements 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 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 guideline is most reasonably ensured if those who must put such guidelines into use 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 Technical Specification 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 — Checklist for preoperative extracorporeal circulation equipment setup

1 Scope

This Technical Specification covers the activities performed by perfusionists 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.

2 Requirements

2.1 Patient information

2.1.1 Patient interviewed

Interview the patient and/or review the patient's records, as per hospital protocol.

2.1.2 Patient identity confirmed

2.1.2.1 Confirm the patient's identity from the patient's chart and with the circulator nurse and verify.

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

2.1.3 Medical record number transcribed and verified

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.

2.1.4 Allergies verified

Review the patient's medical record to determine whether the patient has any known or reported allergies and record such information on any chart-work associated with the procedure.

2.1.5 Blood bank number verified

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

2.1.5.2 Confirm the number of units of blood available.

2.1.6 Blood type, antibodies verified

Review the patient's blood type and possible antibody status by reading laboratory reports in the patient's chart before the procedure.

2.1.7 Chart reviewed

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

2.1.8 Procedure verified

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

2.1.8.2 Confirm the procedure with the surgeon.

2.1.9 Instructions for use read

2.1.9.1 Confirm that the user has read and understood the manufacturer's instructions for use and is aware of any current modifications/changes in order for the products to be operated and used safely.

2.1.9.2 Ensure this before the products are used, including before the preparation period.

2.2 Sterility/cleanliness

2.2.1 Components checked for package integrity/expiration dates

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

2.2.2 Lot numbers

Record the lot numbers of components (oxygenator, reservoir, circuit), as well as the identification of the pump consoles.

2.2.3 Equipment clean

Verify that reusable equipment is blood-free and clean prior to assembly.

2.2.4 Heat exchanger(s) leak-tested

2.2.4.1 For the water phases of all heat exchanger components, connect water source(s) with circulating water and visually verify that they are free from water leakage into the blood pathway(s) prior to adding fluid priming volume.

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

2.2.5 Maintenance

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

2.3 Pumps[1)]

2.3.1 Electrical

2.3.1.1 Power cord connection secured

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

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

1) All pumps, including arterial, and those used with subsystems such as vents, cardioplegia and suckers.

2.3.1.1.3 Ensure that no electrical power cord compromises patient electrical isolation.

2.3.2 Batteries charged and functional

Verify that all battery-powered devices are sufficiently charged and that each device is functional, by disconnecting the AC power source.

2.3.3 Speed controls operational

2.3.3.1 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.

2.3.3.2 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. Verify correct roller pump direction before use.

2.3.4 Rollers rotate freely

Verify that each roller rotates freely by manually rotating it before placing tubing in the roller pump housing, to confirm freedom of motion and absence of jammed bearings. Verify that tubing is free of kinks or torsion.

2.3.5 Pump head rotation smooth and quiet

2.3.5.1 Ensure that all pumps rotate smoothly after tubing has been installed.

2.3.5.2 Ensure that all pumps rotate quietly when filled with fluid during recirculation.

2.3.6 Occlusion(s) set

Set the degree of occlusion of all roller pumps properly, to ensure effective displacement, low trauma and low spallation. If automatic occlusion mode exists, perform a verification in accordance with manufacturer's instructions for use.

2.3.7 Flow probe(s) in correct direction and calibrated

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

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

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

2.3.9 Holders secured

Secure the tubing holders on the inlet and outlet sides of the roller pump housing so as to prevent tubing slippage or movement within the roller pump head.

2.3.10 Servo-regulated connections tested

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

2.3.11 Coupling of centrifugal pump secured

Check that the mechanical position of the centrifugal pump is secure for proper magnetic field coupling and electrical mounting on the pump console.

2.3.12 Pumps functional

Test and verify that all pumps are properly functional.

2.4 Cardioplegia

2.4.1 Solutions checked

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

2.4.2 Water-to-blood leaks absent

Test the cardioplegia delivery system heat exchanger water compartment before priming and verify that it is leak-free.

2.4.3 System debubbled

Ensure that the cardioplegia delivery system is free of air bubbles after fluid priming.

2.4.4 Leak-free after pressurization

Check that the cardioplegia delivery does not leak with pressurization to clinically relevant pressures.

2.5 Gas supply

2.5.1 Gas line connections secured

Verify that all sources of gas supply to the circuit are secure.

2.5.2 Source and appropriate connections of gas verified

Verify that all gas supply lines are connected to the appropriate sources.

2.5.3 Flow meter/gas blender functional

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

2.5.4 Hoses leak-free

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

2.5.5 Gas exhaust unobstructed

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

2.5.6 Inhalational gas scavenge line functional

Check that any device or tubing configuration connected to the oxygenator gas exhaust and intended to remove residual anaesthetic vapours is leak-free and operating properly.

2.5.7 Gas sensor used

Using an in-line oxygen analyser in the gas delivery tubing, verify that the gas mixtures are correct.

2.5.8 Operating pressures for gas sources verified

Verify the use of the proper operational pressures for all gas sources.

2.5.9 Gas filter checked

Check the gas filter before use.

2.6 Vacuum supply

2.6.1 Vacuum line connections secured

Check that all sources of vacuum supply to the circuit are secure.

2.6.2 Source and appropriate connections of vacuum supply verified

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

2.6.3 Operating pressures for vacuum sources verified

Verify the use of proper operational pressures for all vacuum sources.

2.7 Components

2.7.1 Connections/stopcocks/caps secured

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

2.7.2 Appropriate lines clamped and shunts closed

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

2.7.3 Tubing direction traced and verified as correct

Manually trace all tubing to verify that the direction of the intended blood/fluid/gas flow is correct.

2.7.4 No kinks noted

Check that all tubing is kink-free.

2.7.5 One-way valve(s) verified to be in correct direction

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

2.7.6 System debubbled

2.7.6.1 Check that all system components and tubing are free of visible bubbles.

2.7.6.2 A carbon dioxide flush may be used as an aid to debubbling; if this technique is employed, verify completion.

2.7.7 Confirmed as leak-free after pressurization

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

2.7.8 Patency of arterial line/cannula verified

Verify that the systemic flow tubing is in unrestricted continuity with the patient's arterial circulation.

2.8 Safety mechanisms

2.8.1 Alarms operational, audible and engaged

2.8.1.1 Ensure that all alarms or alerts are turned on and have been verified and tested to be functioning properly according to the manufacturer's instructions for use.

2.8.1.2 Set audible warning devices to sound at appropriate levels according to institutional protocol.

2.8.2 Arterial filter/bubble trap debubbled

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

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

Verify that all hard-shell reservoirs intended to be vented to atmosphere are properly vented to atmosphere.

2.8.4 Venous line occluder(s) calibrated and tested

Ensure that electromechanical venous tubing occluders are calibrated and verified to be functioning appropriately.

2.8.5 Devices securely attached to console

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

2.8.6 Electromechanical arterial line occluder functioning

Verify that electromechanical arterial line occluders are functioning appropriately.

2.9 Assisted venous return

2.9.1 Cardiotomy positive pressure relief valve tested

Test positive pressure relief valves either integral or attached to the hard-shell cardiotomy/venous reservoir.

2.9.2 Negative pressure-relief valve unobstructed

Test negative pressure-relief valves either integral or attached to the hard-shell cardiotomy/venous reservoir.

2.9.3 Vacuum regulator tested

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

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

2.9.4.1 Verify the operational speed control and functionality.

2.9.4.2 Verify the correct flow probe direction visually.

2.9.4.3 Verify that all bypass lines are debubbled and clamped.

2.10 Monitoring

2.10.1 Temperature probes in place

Verify that the location of all temperature probes (patient and circuit including water sources) are in place and functioning.

2.10.2 Pressure transducers/monitors calibrated on proper scale(s)

Verify that all pressure transducers (patient and circuit) have been calibrated, are on appropriate scales and are functioning.

2.10.3 In-line sensor(s) calibrated

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

2.10.4 Oxygen analyser calibrated

Ensure that the oxygenator sweep gas analyser has been calibrated at low and high (e.g. 21 % and 100 % oxygen) delivery values.

2.11 Anticoagulation

2.11.1 Heparin time and dose confirmed

Confirm the dose and time of administration of systemic heparin anticoagulation.

2.11.2 Anticoagulation tested and reported

Confirm, document and verbally report systemic anticoagulation.

2.12 Temperature control

2.12.1 Water source(s) connected and functional

Verify that all water sources for circuit heat exchangers (e.g. oxygenator, cardioplegia) are connected and circulating water appropriately.

2.12.2 Temperature range(s) tested and functional

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

2.12.3 Water lines unobstructed

Verify that all heat exchanger water lines (inlet and outlet) are unobstructed.

2.13 Supplies

2.13.1 Tubing clamps available

Ensure that an adequate number of appropriately sized tubing clamps have been counted and are readily available to the operator for the anticipated duration of the case.

2.13.2 Drugs available and properly labelled

2.13.2.1 Ensure that all drugs that might be required to be administered to the patient are readily available.

2.13.2.2 If such drugs are pre-drawn into syringes, ensure that the syringes are clearly labelled with the drug name and dosage.

2.13.3 Solutions available

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

2.13.4 Blood products available

Verify that all blood products that might be required to be administered to the patient are readily available.

2.13.5 Sampling syringes/laboratory tubes and supplies available

Ensure that syringes in appropriate sizes and laboratory sample tubes/supplies are available for the number of anticipated uses.

2.13.6 Inhalational anaesthetic correct

Verify the correctness of the anaesthetic vaporizer.

2.13.7 Vaporizer operational and filled

Verify that the anaesthetic vaporizer is operational and filled with the appropriate anaesthetic.

2.14 Backup

2.14.1 Hand cranks available

Ensure that manual hand cranks used to operate systemic and other pumps are readily available in the event that electrical power is interrupted.

2.14.2 Emergency lighting available

Ensure that portable lighting (e.g. flashlights) is readily available and tested for proper functioning in the event that room lighting is interrupted.

2.14.3 Backup full oxygen tank with flow meter available

Ensure that a secondary source of oxygen gas, including a flow meter to supply the oxygenator, is readily available in the event wall oxygen sources are interrupted. Verify that it is full by opening the valve.

2.14.4 Duplicate circuit components and hardware available

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

2.14.5 Ice available

Confirm a source of ice for heat exchanger(s) and that it is readily available.