TECHNICAL SPECIFICATION

ISO/TS 23810

Second edition
2012-04-15

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

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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 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.

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to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn.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again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.

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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.

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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.

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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.

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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.

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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.

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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.

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2.2.3 Equipment clean

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

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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.

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

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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.

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

2.3.6 Occlusion(s) set

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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.

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