TECHNICAL SPECIFICATION

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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

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Foreword

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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.