TECHNICAL SPECIFICATION

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to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn.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again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.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