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to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn.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again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.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