SLOVENSKI STANDARD
SIST EN 12022:2000

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Izmenjevalniki krvnih plinov

Blood gas exchangers

Blutgasaustauscher

Echangeurs gaz/sang extra corporels

Ta slovenski standard je istoveten z: **EN 12022:1999**

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment

SIST EN 12022:2000 **en**

EUROPEAN STANDARD
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Descriptors: medical equipment, oxygenators, disposable equipment, definitions, specifications, physical properties, performance evaluation, flow rate, gases, blood, tests, testing conditions, information, packing, marking

English version

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This European Standard was approved by CEN on 10 June 1998.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

Contents

Foreword

This European Standard has been prepared by Technical Committee CEN/TC 205 "Non-active medical devices", the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by July 1999, and conflicting national standards shall be withdrawn at the latest by July 1999.

This European Standard is based on ISO 7199 'Cardiovascular implants and artificial organs - Blood-gas exchangers (oxygenators)', prepared by Technical Committee TC 150 of the International Organization for standardization.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

This European Standard is intended to ensure that devices designed to effect the exchange of gases in support of, or as a substitution for the normal respiratory function of the lungs have been adequately tested for both their safety and function, and that extracorporeal device characteristics are appropriately disclosed when labelling the device.

This European Standard therefore contains recommended procedures to be used for evaluation of extracorporeal blood gas exchangers. Type test procedures for determination of the gas transfer, blood cell damage and heat exchanger performance are described, although limits for these characteristics are not specified. Ready identification of the performance characteristics should, however, assist the user in the selection of a blood gas exchanger which will suit the needs of the patient.

This European Standard also includes minimum reporting requirements, which will allow the user to compare performance characteristics of blood gas exchangers of different designs in a standard way.

This European Standard makes reference to other standards where methods for determination of characteristics common to medical devices can be found.

No provisions have been made for quantification of microbubble generation or for non-formed elements of bovine blood, due to the fact that there is currently no consensus regarding satisfactorily reproducible test methods.

Requirements for animal and clinical studies have not been included in this European Standard. Such studies can be part of a manufacturer's quality system.

This European Standard contains only those requirements that are specific to blood gas exchangers. Non-specific requirements are covered by references to other standards listed in the normative references section. Since non-toxicity is anticipated to be the subject of a future standard, this European Standard does not cover non-toxicity.

1 Scope

This European Standard specifies requirements for sterile, single-use, extracorporeal blood gas exchangers intended for supply of oxygen to, and removal of carbon dioxide from, the blood of humans.

This European Standard also applies to heat exchangers that are integral parts of blood gas exchangers and to external equipment unique to the use of the device.

This European Standard does not apply to:

- implanted blood gas exchangers;
- liquid exchangers;
- extracorporeal circuits (blood tubing);
- separate heat exchangers;
- separate ancillary devices.

2 Normative references

This European Standard incorporates, by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references, the latest edition of the publications referred to applies.

EN 550	*Sterilization of medical devices - Validation and routine control of ethylene oxide sterilization*
EN 552	*Sterilization of medical devices - Validation and routine control of sterilization by radiation*
EN 554	*Sterilization of medical devices - Validation and routine control of sterilization by moist heat*
EN 556	*Sterilization of medical devices - Requirements for medical devices to be labelled 'Sterile'*
EN ISO 10993-1	*Biological evaluation of medical devices - Part 1: Evaluation and testing (ISO 10993-1:1997)*
EN ISO 10993-7	*Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (ISO 10993-7:1995)*

EN ISO 10993-11	*Biological evaluation of medical devices - Part 11: Test for systemic toxicity (ISO 10993-11:1993)*
EN 46001	*Quality systems - Medical devices: Particular requirements for the application of EN ISO 9001*
EN 46002	*Quality systems - Medical devices: Particular requirements for the application of EN ISO 9002*

3 Definitions

For the purposes of this European Standard, the following definitions apply:

3.1 blood gas exchanger: Extracorporeal device designed to temporarily supplement, or be a substitute for, the respiratory function of the lung.

3.2 blood pathway: Paths of the blood gas exchanger containing blood during intended clinical use.

3.3 bovine blood: Whole, or diluted with physiological saline solution, anticoagulated blood from cattle.

3.4 gas pathway: Parts of the blood gas exchanger containing the ventilation gas during intended clinical use.

3.5 heat exchanger: Component that is intended to control the temperature of the circulating blood and/or priming solution.

3.6 heat exchanger performance factor: Ratio R of the difference between the temperature of blood at the outlet and inlet of the blood gas exchanger, and the difference between the temperature of the blood at the inlet of the blood gas exchanger and the temperature of the water at the inlet of the heat exchanger, using the following equation:

$$R = \frac{B_{To} - B_{Ti}}{W_{Ti} - B_{Ti}}$$

where

B_{To} is the temperature of the blood at the outlet of the blood gas exchanger;

B_{Ti} is the temperature of the blood at the inlet of the blood gas exchanger; and

W_{Ti} is the temperature of the water at the inlet of the heat exchanger.

3.7 integral part: Part that is connected to the blood gas exchanger so that it cannot normally be separated by the user.

3.8 operating variables: Setting of parameters which affect the function of the device.

3.9 platelet percentage reduction: Percentage reduction of platelets, compared to a baseline level, contained in a circuit incorporating a blood gas exchanger less the percentage reduction in an identical control circuit without a blood gas exchanger as a function of time.

3.10 plasma-free haemoglobin generation: Concentration of plasma-free haemoglobin in a circuit incorporating a blood gas exchanger less the concentration in an identical control circuit without a blood gas exchanger as a function of time.

3.11 white blood cell percentage reduction: Percentage reduction of white blood cells contained in a circuit incorporating a blood gas exchanger less the percentage reduction in an identical control circuit without a blood gas exchanger as a function of time.

4 Requirements

4.1 Biological characteristics

4.1.1 *Sterility and non-pyrogenicity*

The blood pathway shall be sterile and non-pyrogenic.

Compliance shall be verified in accordance with 5.2.1.

4.1.2 *Biocompatibility*

Parts of the blood pathway shall be biocompatible with respect to their intended use.

Compliance shall be verified in accordance with 5.2.2.

4.2 Physical characteristics

4.2.1 *Blood pathway integrity*

When tested in accordance with 5.3.1, the blood pathway shall not leak.

4.2.2 *Heat exchanger fluid pathway integrity*

When tested in accordance with 5.3.2, the heat exchanger fluid pathway shall not leak.

4.2.3 *Blood volumes*

When tested in accordance with 5.3.3, the volume of the blood pathway shall be within the tolerance specified by the manufacturer (see 6.3).