BRITISH STANDARD

BS EN
12022:1999

# Blood-gas exchangers



The European Standard EN 12022:1999 has the status of a British Standard

ICS 11.040.10

# National foreword

This British Standard is the English language version of EN 12022:1998.

The UK participation in its preparation was entrusted to Technical Committee CH/23, Cardiovascular implants, dialysis systems and oxygenators, which has the responsibility to:

— aid enquirers to understand the text;

— present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;

— monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this committee can be obtained on request to its secretary.



**Cross-references**

The British Standards which implement international or European publications referred to in this document may be found in the BSI Standards Catalogue under the section entitled “International Standards Correspondence Index”, or by using the “Find” facility of the BSI Standards Electronic Catalogue.

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**Summary of pages**

This document comprises a front cover, an inside front cover, the EN title page, pages 2 to 8, an inside back cover and a back cover.

This British Standard, having been prepared under the direction of the Health and Environment Sector Committee, was published under the authority of the Standards Committee and comes into effect on 15 June 1999



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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

# EN 12022

January 1999

ICS 11.040.10

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



English version

# Blood gas exchangers

Echangeurs gaz/sang extra corporels

Blutgasaustauscher

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.

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**CEN**

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

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



Ref. No. EN 12022:1999 E

## 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.



## Contents

## 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**).

#### 4.2.4 *Connectors*

Connectors for connection to the blood pathway shall, when tested in accordance with **5.3.4**, allow a secure connection.

NOTE 1 Connectors of a type that allows connection of tubes with an inner diameter of 4,8 mm, 6,3 mm, 9,5 mm or 12,7 mm, or a type that complies with Figure 1 of EN 1283:1996, or a type that complies with EN 1707 have been used.

When tested in accordance with **5.3.4**, the gas inlet connection to the gas pathway shall not separate.

Connectors for the heat exchanger fluid pathway shall be capable of connection using fast couplings.

NOTE 2 Connectors corresponding to Figure 3 of EN 1283:1996 are considered as one way to comply with this requirement.

### 4.3 Performance characteristics

#### 4.3.1 *Blood-gas exchanger oxygen and carbon dioxide transfer rates*

When determined in accordance with **5.4.1**, the oxygen and carbon dioxide transfer rates shall be within the range of values specified by the manufacturer (see **6.3**).

#### 4.3.2 *Heat exchanger performance factor*

When determined in accordance with **5.4.2**, the heat exchanger performance factors shall be within the range of values specified by the manufacturer (see **6.3**).

#### 4.3.3 *Blood cell damage*

When determined in accordance with **5.4.3**, the increased concentration of plasma-free haemoglobin and the percentage reduction of platelets and white blood cells shall be within the range of values specified by the manufacturer (see **6.3**).

#### 4.3.4 *Time-dependent performance changes*

When determined in accordance with **5.4.1**, the oxygen and carbon dioxide transfer rates shall be within the range of values specified by the manufacturer (see **6.3**).

## 5 Compliance tests and measurements

### 5.1 General

Compliance tests and measurements shall be performed with the device under test prepared according to the manufacturer's instructions for intended clinical use.

Operating variables shall be those specified by the manufacturer for intended clinical use unless otherwise specified in this European Standard.

Unless otherwise stated in this European Standard, the temperature of test liquids shall be $(37 \pm 1)$ °C.

If the relationship between variables is non-linear, sufficient determinations shall be made to permit valid interpolation between data points.

The test or measurement procedures are to be regarded as reference procedures. Other procedures can be accepted provided that the alternative procedure has been shown to be of comparable precision and reproducibility.

### 5.2 Biological characteristics

#### 5.2.1 *Sterility and non-pyrogenicity*

Compliance shall be verified by inspection of the manufacturer's documentation on sterilization and pyrogen testing, which shall be in accordance with EN 550, EN 552, EN 554, EN 556 and EN ISO 10993-11, as applicable.

#### 5.2.2 *Biocompatibility*

Compliance shall be verified by test or by inspection of the manufacturer's documentation on biocompatibility for the finished device, which shall be in accordance with EN ISO 10993-1 and EN ISO 10993-7.

### 5.3 Physical characteristics

#### 5.3.1 *Determination of blood pathway integrity*

##### 5.3.1.1 *Test liquid*

The test liquid shall be water.

##### 5.3.1.2 *Procedure*

Place the device under test in an appropriate test circuit. Subject the blood pathway of the device to a pressure which is 1,5 times the maximum pressure specified by the manufacturer for intended clinical use (see **6.3**). If no maximum pressure is specified, the test shall be performed at 40 kPa. Maintain this pressure for 6 h, or as long as is specified by the manufacturer for intended clinical use (see **6.3**), and visually inspect the device for the emergence of water.

#### 5.3.2 *Determination of heat exchanger fluid pathway integrity*

##### 5.3.2.1 *Test liquid*

The test liquid shall be water.

##### 5.3.2.2 *Procedure*

Place the device under test in an appropriate test circuit. Subject the heat exchanger fluid pathway to a pressure which is 1,5 times the maximum pressure specified by the manufacturer for intended clinical use (see **6.3**). If no maximum pressure is specified, the test shall be performed at 350 kPa. Maintain this pressure for 6 h, or as long as is specified by the manufacturer for intended clinical use (see **6.3**), and visually inspect the device for emergence of water.

#### 5.3.3 *Blood volumes*

##### 5.3.3.1 *Test liquid*

The test liquid shall be bovine blood or water.

##### 5.3.3.2 *Procedure*

The volume of the blood pathway shall be determined over the range of operating variables specified by the manufacturer for intended clinical use (see **6.3**).

#### 5.3.4 *Connectors*

##### 5.3.4.1 *Procedure*

The connection shall be assembled in accordance with the manufacturer's instructions for use.

The connection shall withstand an axial pull force of 15 N for 15 s without separating.

### 5.4 Performance characteristics

#### 5.4.1 *Oxygen and carbon dioxide transfer rates*

##### 5.4.1.1 *Test media*

The test liquid for the blood pathway shall be bovine blood. The test medium for the gas pathway shall be gas of known oxygen, nitrogen and carbon dioxide concentrations.

##### 5.4.1.2 *Procedure*

Place the device under test in an appropriate test circuit. Perform tests using the following blood inlet conditions during determination of oxygen and carbon dioxide transfer rates:

— oxyhaemoglobin percentage: $(65 \pm 5)$ %;

— haemoglobin: $(12 \pm 1)$ g/dl;

— base excess: $(0 \pm 5)$ mmol/l;

— $pCO_2$: $(6{,}0 \pm 0{,}7)$ kPa.

Oxygen and carbon dioxide transfer rates shall be determined over the manufacturer's specified range of operating variables (see **6.3**).

Between each set of requirements, the blood flow shall be kept at the maximum specified by the manufacturer for intended clinical use (see **6.3**).

Determination of oxygen and carbon dioxide transfer rates shall be made at the initiation of the test. For time-dependent determinations, measurements shall be performed at initiation of the test and then at 1 h, 3 h and 6 h after the start of the test. As applicable, further determinations shall be made at 6 h intervals.

NOTE 1 In vitro tests as well as tests using cattle are acceptable.

NOTE 2 The blood can be exchanged for fresh blood as required in oxygen and carbon dioxide transfer measurements.

NOTE 3 Data need not be collected at the conditions specified. Approximations obtained by reasonable interpolation are accepted.

**5.4.2** ***Heat exchanger performance factor***

**5.4.2.1** *Test liquid*

The test liquid for the blood pathway shall be bovine blood or water.

**5.4.2.2** *Procedure*

Place the device under test in an appropriate test circuit. Perform the test in vitro under the following conditions:

— blood inlet temperature, $B_{Ti}$: (30 ± 1) °C;

— water inlet temperature, $W_{Ti}$: (40 ± 1) °C.

The determination of heat exchanger performance factors shall be made over the manufacturer's specified range of operating variables (see **6.3**).

**5.4.3** ***Blood cell damage***

**5.4.3.1** *Test media*

The test liquid for the blood pathway shall be heparinized bovine blood. The test medium for the gas pathway shall be gas of suitable oxygen, nitrogen and carbon dioxide concentrations.

**5.4.3.2** *Procedure*

Two sets of appropriate, identical circuit components, including a pump, connecting tubing, a reservoir (as specified by the manufacturer and of suitable size relative to the device under test) and a heat exchanger, shall be assembled. The device under test shall be placed in one of the circuits. The blood pathway test liquid volumes shall, at the initiation of the test, be within 1 % of each other. Perform the test in vitro using the conditions given in Table 1, and taking samples for the measurement of parameters as given in Table 2.



**Table 1 — Conditions for blood cell damage test**

| Item | Level | Maximum variation |
|---|---|---|
| Blood flow rate | The maximum specified by the manufacturer for intended clinical use (see **6.3**), or 6 l/min, whichever is smaller | ±5 % |
| Gas flow rate | The maximum specified by the manufacturer for intended clinical use (see **6.3**) | ±5 % |
| $pCO_2$ | 5,3 kPa | ±0,7 kPa |
| Base excess | 0 | ±5 mmol/dl |
| Blood glucose | 10 mmol/dl | ±5 mmol/dl |
| Haemoglobin | 12 g/dl | ±1 g/dl |

**Table 2 — Test samples for blood cell damage test**

| Parameter | Prior to test | 10 min | 30 min | 180 min | 360 min |
|---|---|---|---|---|---|
| Plasma-free haemoglobin | X | | X | X | X |
| WBC | X | | X | X | X |
| Platelets | X | | X | X | X |
| Blood-gas values:<br>$pCO_2$<br>$pO_2$<br>pH | | X | X | X | X |
| Base excess | | | | | |
| Haemoglobin | X | X | X | X | X |
| Glucose | X | | | | |
| ACT | X | | | | |
| Temperature | X | X | X | X | X |
| Flow rates | X | X | X | X | X |

## 6 Information supplied by the manufacturer

### 6.1 Information to be given on the blood-gas exchanger

The following information shall be given on the blood-gas exchanger:

a) the manufacturer's identification;

b) batch, lot or serial number designation;

c) model designation;

d) the direction of blood and/or gas and/or water flows, if necessary;

e) the minimum and operating reservoir levels, where appropriate.

### 6.2 Information to be given on the packaging

#### 6.2.1 *Information to be given on the unit container*

The following information shall be visible through or given on the unit container:

a) the manufacturer's name and address;

b) description of contents;

c) model designation;

d) statement on sterility and non-pyrogenicity;

e) expiry date;

f) batch, lot or serial number designation;

g) statement to read instructions before use;

h) special handling or storage conditions;

i) statement on single-use.

NOTE Symbol 4.1 of EN 980:1996 can be used.

#### 6.2.2 *Information to be given on the shipping container*

The following information shall be given on the shipping container:

a) the manufacturer's name and address;

b) description of contents, including number of units;

c) model designation;

d) statement on sterility and non-pyrogenicity;

e) expiry date;

f) special handling, storage or unpacking instructions.

### 6.3 Information to be given in the accompanying documents

**6.3.1** Each shipping container shall contain an "Instructions for Use" leaflet with the following information:

a) the manufacturer's address and telephone or telefax number;

b) model designation;

c) required ancillary equipment;

d) instructions on necessary, special or unique procedures as applicable;

e) directions for placing the blood-gas exchanger in a support or operational fixture;

f) placement, type and securing of tubing connections;

g) location and purpose of additional entry or exit ports;

h) heat exchanger priming and operation;

i) priming procedure;

j) direction of blood, gas and water flows;

k) general operating procedures for normal use;

l) a recommended procedure for intraoperative replacement of a blood-gas exchanger;

m) maximum and minimum recommended blood flow rates;

n) maximum and minimum operating volumes of the blood pathway, including any integral reservoir;

o) maximum and minimum specified gas flow rates;

p) heat exchanger performance factors;

q) residual blood volume;

r) oxygen and carbon dioxide transfer rates;

s) pressure limitations for blood, water and gas pathways;

t) a statement that the following information is available upon request:

— sterilization method;

— a list of materials of the blood pathway;

— data on plasma leakage across any semi-permeable membrane, if applicable;

— blood pathway pressure drop at the maximum blood flow rate specified by the manufacturer for intended clinical use;

— gas pathway pressure drop at the maximum blood and gas flow rates specified by the manufacturer for intended use;

— data related to blood cell damage;

— data on particle release from the blood-gas exchanger;

— relevant tolerances for data presented.

**6.3.2** The following information shall be given in the accompanying documents in a prominent form:

a) pressure limitations;

b) flow rate limitations;

c) blood level limitations;

d) other device limitations.

## 7 Packaging

Packaging shall comply with the appropriate requirements of EN 46001 or EN 46002.

## Annex A (informative)

## Bibliography

EN 980, *Terminology, symbols and information provided with medical devices — Graphical symbols for use in the labelling of medical devices.*

EN 1283:1996, *Haemodialysers, haemofilters and haemoconcentrators.*

EN 1707, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical devices Part 2: Lock fittings.*

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