INTERNATIONAL STANDARD

ISO 7199

Third edition
2016-11-15

Cardiovascular implants and artificial organs — Blood-gas exchangers (oxygenators)

Implants cardiovasculaires et organes artificiels — Échangeurs gaz/sang extracorporels (oxygénateurs)

Reference number
ISO 7199:2016(E)

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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. 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. www.iso.org/patents

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For an explanation on 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: http://www.iso.org/iso/foreword.html

The committee responsible for this document is ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*.

This third edition cancels and replaces the second edition (ISO 7199:2009), which has been technically revised.

It also incorporates the Amendment ISO 7199:2009/Amd.1:2012.

Introduction

This document is intended to ensure that devices designed to affect 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 document therefore contains procedures to be used for evaluation of extracorporeal blood-gas exchangers (oxygenators). 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 an oxygenator that will suit the needs of the patient.

This document also includes minimum reporting requirements, which will allow the user to compare performance characteristics of oxygenators of different designs in a standard way.

This document makes reference to other International Standards in which 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 because there currently is no consensus regarding satisfactorily reproducible test methods.

Requirements for animal and clinical studies have not been included in this document. Such studies may be parts of a manufacturer's quality system.

This document contains only those requirements that are specific to oxygenators. Non-specific requirements are covered by references to other International Standards listed in the normative references clause. Since non-toxicity is anticipated to be the subject of a future horizontal/level 1 standard, this document does not cover non-toxicity.

Cardiovascular implants and artificial organs — Blood-gas exchangers (oxygenators)

1 Scope

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

This document also applies to heat exchangers and arterial filters that are integral parts of the oxygenator.

This document also applies to external equipment unique to the use of the oxygenator.

This document does not apply to

— implanted oxygenators,

— liquid oxygenators,

— extracorporeal circuits (blood tubing),

— separate heat exchangers,

— separate ancillary devices, and

— separate arterial line filter.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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.

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 10993-4, *Biological evaluation of medical devices — Part 4: Selection of tests for interaction with blood*

ISO 10993-7, *Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals*

ISO 10993-11, *Biological evaluation of medical devices — Part 11: Tests for systemic toxicity*

ISO 11135, *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 11607-2, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes*

ISO 15675, *Cardiovascular implants and artificial organs — Cardiopulmonary bypass systems — Arterial blood line filters*

ISO 17665-1, *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

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 http://www.iso.org/obp

3.1
blood-gas exchanger
oxygenator
extracorporeal device designed to supplement, or be a substitute for, the respiratory function of the lungs

3.2
blood pathway
paths of the oxygenator containing blood during intended clinical use

3.3
gas pathway
parts of the oxygenator containing the ventilation gas during intended clinical use

3.4
heat exchanger
component that is intended to control the temperature of the circulating blood or priming solution

3.5
heat exchanger performance factor
R
ratio of the difference between the temperature of blood at the outlet of the oxygenator and the temperature of blood at the inlet of the oxygenator to the difference between the temperature of the water at the inlet of the heat exchanger and the temperature of blood at the inlet of the oxygenator

3.6
integral arterial filter
component that is intended to filter particles such as blood clots, debris, and gas emboli from the blood

3.7
filtration efficiency
ability of the filter to remove particles from the simulated blood suspension test fluid, expressed as a percentage

3.8
integral part
part that is connected to the oxygenator and cannot normally be separated by the user

3.9
operating variables
settings of controls that affect the function of the device

3.10
platelet reduction
percentage reduction of platelets contained in a circuit incorporating an oxygenator, as a function of time

3.11
plasma-free haemoglobin level
concentration of plasma-free haemoglobin in a circuit incorporating an oxygenator, as a function of time

3.11.1
normalized index of hemolysis
NIH
grams of plasma-free hemoglobin released after pumping 100 l of blood

$$\mathrm{NIH\,(g\ /\ 100\ l)} = \Delta f_{\mathrm{Hb}} \cdot V \cdot \frac{100 - \mathrm{Hct}}{100} \cdot \frac{100}{Q \cdot t} \tag{1}$$

where

Δf_{Hb} is the increase of plasma free hemoglobin concentration (g/l) over the sampling time interval;

V is the circuit volume (l);

Q is the flow rate (l/min);

Hct is the hematocrit (%);

t is the sampling time interval (min)

3.12
white blood cell reduction
percentage reduction of white blood cells contained in a circuit incorporating an oxygenator, as a function of time

3.13
residual blood volume
difference between the priming volume of the unit and the blood volume that can be extracted

3.14
blood analogue
test solution which simulates blood viscosity between $2{,}0 \times 10^{-3}$ Pa·s (2,0 cP), to $3{,}5 \times 10^{-3}$ Pa·s (3,5 cP)

3.15
predicate oxygenator
similar oxygenator to the test oxygenator that has previously been approved and used for the same intended clinical use

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

All 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 tolerances 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 ISO 8637:2010, Figure 1, or a type that complies with ISO 594-2, have been found satisfactory.

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 being connected using fast couplings.

NOTE 2 Connectors corresponding to ISO 8637:2010, Figure 3 are considered as one way to comply with this requirement.

4.3 Performance characteristics

4.3.1 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 Integral arterial filtration efficiency

When tested in accordance with 5.4.5, filtration efficiency of any individual device should be at least 80 % when tested with particles that are 20 % larger than the nominal pore size of the filter.

4.3.4 Integral arterial filter flow rate capacity

When tested in accordance with 5.4.6, test results will demonstrate the flow rate and pressure limitation(s) to ensure safe and effective performance, as specified by the manufacturer.

4.3.5 Integral arterial filter air handling capability

When tested in accordance with 5.4.7, test results shall demonstrate the air-handling capability, as specified by the manufacturer.

4.3.6 Blood cell damage

4.3.6.1 Plasma-free haemoglobin

When determined in accordance with 5.4.3, the increased concentration of plasma-free haemoglobin shall be within the range of values specified by the manufacturer.

The haemolysis results shall be reported as mg/dl and NIH.

4.3.6.2 Platelet reduction and white blood cell reduction

When determined in accordance with 5.4.3, the percentage reduction of platelets and the percentage reduction of white blood cells shall be within the range of values specified by the manufacturer.

4.3.7 Time-dependent performance changes

When determined in accordance with 5.4.1, the oxygen and carbon dioxide transfer rates shall remain consistent within the range of values over the duration of the testing specified by the manufacturer.

4.3.8 Shelf life

When tested in accordance with 5.4.4, test results should demonstrate the rated shelf life, as specified by the manufacturer.

5 Tests and measurements to determine compliance with this document

5.1 General

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

5.1.2 Operating variables shall be those specified by the manufacturer for intended clinical use, unless otherwise specified.

5.1.3 Unless otherwise stated, the temperature of test liquids shall be (37 ± 1) °C.

5.1.4 If the relationship between variables is nonlinear, sufficient determinations shall be made to permit valid interpolation between data points.

5.1.5 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, in accordance with ISO 17665-1, ISO 11135, ISO 11137-1 and 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, in accordance with ISO 10993-1 and ISO 10993-7, as applicable.

5.3 Physical characteristics

5.3.1 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 that is 1,5 × the maximum pressure specified by the manufacturer for intended clinical use. If no maximum pressure is specified, the test shall be performed at 152 kPa for 6 h or as long as it is specified by the manufacturer for clinical use. Visually inspect the device for leakage of water.

5.3.2 Heat exchanger water 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 1,5 × that specified by the manufacturer for intended clinical use. 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 and visually inspect the device for leakage of water.

5.3.3 Blood volumes

5.3.3.1 Test liquid

The test liquid shall be anticoagulated whole 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).

5.3.3.3 Residual blood volume

Residual blood volume is determined by holding the unit in its most advantageous drainage position for 20 s past the time that air first appears at the port being used for drainage until no remaining volume is noted in the device.

5.3.4 Connectors

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

The connection shall withstand a 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 anticoagulated blood. The test medium for the gas pathway shall be gas of known oxygen, nitrogen and carbon dioxide concentrations.

5.4.1.2 Procedure

5.4.1.2.1 General

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 ± 5);

— haemoglobin: (12 ± 1) g/dl;

— base: (0 ± 5) mmol/l;

— partial pressure of carbon dioxide in blood, p_{CO2}: (6,0 ± 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 measurements, 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 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.

In vitro tests as well as tests using an appropriate animal model are acceptable.

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

Data need not be collected at the precise conditions specified. Approximations obtained by reasonable interpolation are acceptable.

5.4.1.2.2 Clinical conditions

For additional information, the following test conditions should be considered.

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:

— change temperature to a range 28 °C and 18 °C ± 1 °C

— oxyhaemoglobin percentage: (65 ± 5);

— haemoglobin: (8 ± 2) g/dl;

— base: (0 ± 5) mmol/l;

— partial pressure of carbon dioxide in blood, p_{CO2}: (6,0 ± 0,7) kPa.

5.4.2 Heat exchanger performance factor

5.4.2.1 Test liquid

The test liquid for the blood pathway shall be anticoagulated 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, $T_{\text{in,blood}}$: (30 ± 1) °C;

— water inlet temperature, $T_{\text{in,water}}$: (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).

5.4.2.3 Equation

The heat exchanger performance factor is given by the following equation:

$$R = \frac{T_{\text{out,blood}} - T_{\text{in,blood}}}{T_{\text{in,water}} - T_{\text{in,blood}}} \tag{2}$$

where

$T_{\text{out,blood}}$ is the temperature of the blood at the outlet of the oxygenator, in °C;

$T_{\text{in,blood}}$ is the temperature of the blood at the inlet of the oxygenator, in °C;

$T_{\text{in,water}}$ is the temperature of the water at the inlet of the heat exchanger, in °C.

5.4.3 Blood cell damage

5.4.3.1 Test media

The test liquid for the blood pathway shall be anticoagulated 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. A predicate device shall be placed in the second test circuit. Priming and debubbling of the circuits by recirculating with an appropriate solution is recommended before blood is added. 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. A sufficient number of paired tests should be performed to support a statistical analysis. The predicate oxygenator should be tested under the same conditions.

The sampling schedule shall be in accordance with Table 2. More frequent sampling times are optional.

5.4.4 Shelf life

Using a validated method, ageing should be performed on final, finished, sterilized, devices in primary packaging in order to determine nominal shelf life.

5.4.5 Filtration efficiency

5.4.5.1 Test liquid

The test liquid shall be glycerin solution or water. The test liquid shall contain 350 to 5 000 particles per ml that are 15 % to 25 % larger than the nominal pore size of the filter.

5.4.5.2 Procedure

Pass 500 ml of the test liquid at room temperature (20 °C to 22 °C) through the device at a flow rate of no less than 100 ml/min and a pressure not exceeding 152 kPa (22 psi) gauge. Determine the pre and post-filtration mean number of particles. The test shall be performed at the manufacturer's recommended flow rates. Calculate the filtration efficiency, using the readings from the size range of the test particles used for each test sample, by subtracting the post-filtration mean number of particles from the pre-filtration mean, dividing the quotient by the pre-filtration mean number of particles, and multiplying by 100 to obtain a percentage.

5.4.6 Integral arterial filter flow rate

5.4.6.1 Test liquid

The test liquid shall be anticoagulated whole blood or blood analogue.

5.4.6.2 Procedure

Place the device under test in an appropriate test circuit. Set the flow rate at the maximum rated flow and monitor the inlet and outlet pressures across the device for 6 h. Measure the flow rate using a calibrated flowmeter. Note any pressure changes during the test.

If anticoagulated whole blood is used this test shall not take into account the effects of formed elements or proteinaceous aggregates.

5.4.7 Air-handling capability of integral arterial filter

5.4.7.1 Test liquid

The test liquid shall be anticoagulated whole blood with a haemoglobin content of (12 ± 1) g/dl.

5.4.7.2 Procedure

Use filter vent tubing as specified in the manufacturer's instructions for use. The length and internal diameter of the vent tubing shall be specified. The back pressure at the maximum test flow shall be 26,6 kPa (3,9 psi) ± 5 %. Use a bubble eliminator to measure any air downstream of the integral filter accumulated over a period of 5 min from bolus injection. At flow rates of 33 %, 67 %, and 100 % of the specified maximum rated flow rate, a bolus of 30 ml of room air for adult oxygenators (for paediatric or infant oxygenators with a maximum flow rate of less than 500 ml/min the bolus shall be 2,5 ml and for maximum flow rates higher than 500 ml/min the bolus shall be increased by 2,5 ml for every 500 ml/min maximum flow rate; the maximum bolus shall be 10 ml) shall be injected as a single bolus. Indication of the air bolus injection point in the test circuit, rate of injection, and type of pump utilized to circulate test liquid should be provided in the test protocol.

5.4.7.3 Results

The results shall be reported as the percentage efficiency of gross air removal.

Table 1 — Conditions for in vitro testing of blood cell damage

Item	Level	Maximum variation
Blood flow rate	The maximum specified by the manufacturer for intended clinical use (see 6.3)	±5 %
Gas flow rate	The maximum specified by the manufacturer for intended clinical use (see 6.3)	±5 %
p_{CO2}	5,3 kPa	±0,7 kPa
Base	0[a]	±5 mmol/l
Blood glucose	10 mmol/l	±5 mmol/l
Haemoglobin	12 g/dl	±1 g/dl

[a] Note that 0 [zero] refers to 24 mmol/l bicarbonate (HCO_3^-).

Table 2 — Sampling schedule

Parameter	Prior to test	Time, after initiation of test min			
		10	30	180	360
Plasma-free haemoglobin	X		X	X	X
White blood cell	X		X	X	X
Platelets	X		X	X	X
Blood gas values p_{CO2} p_{O2} pH Base		X	X	X	X
Haemoglobin	X	X	X	X	X
Glucose	X				
Activated clotting time	X				
Temperature	X	X	X	X	X
Flow rates	X	X	X	X	X

6 Information supplied by the manufacturer

6.1 Information on the oxygenator

The following information shall be given on the oxygenator:

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;

6.2 Information on the packaging

6.2.1 Unit container

The following 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) the words "Read instructions before use." The symbol  may be added before "Read instructions before use';

h) any special handling or storage conditions;

i) statement on single use. The symbol  may be used.

6.2.2 Shipping container

The following information shall appear 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) any special handling, storage or unpacking instructions.

6.3 Information in the accompanying documents

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 oxygenator 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 an oxygenator;

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) air-handling capability;

r) residual blood volume;

s) oxygen and carbon dioxide transfer rates;

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

u) a statement that the following are available upon request:

   1) sterilization method;

   2) a list of materials of the blood pathway;

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

   4) blood pathway pressure drop at the range of blood flow rates specified by the manufacturer for intended clinical use;

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

   6) data related to blood cell damage;

   7) data on particle release from the oxygenator according to the manufacturer's quality control management system;

   8) relevant tolerances for data presented.

6.4 Information in the accompanying documents in a prominent form

The following information shall be given, in prominent form, in the accompanying documents:

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 ISO 11607-1 and ISO 11607-2.

Bibliography

[1] ISO 594-2, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*

[2] ISO 8637:2010, *Cardiovascular implants and extracorporeal systems — Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators*

[3] ISO 13485, *Medical devices — Quality management systems — Requirements for regulatory purposes*

[4] ISO 14971, *Medical devices — Application of risk management to medical devices*

[5] ISO/TS 23810, *Cardiovascular implants and artificial organs — Checklist for preoperative extracorporeal circulation equipment setup*

[6] US Food and Drug Administration. *Guidance for Cardiopulmonary Bypass Oxygenators 510(k) submissions: Final guidance for industry and FDA staff*, issued Nov. 13, 2000

ICS 11.040.40

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