INTERNATIONAL STANDARD

ISO 7199

Second edition
2009-04-15

AMENDMENT 1
2012-02-15

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

AMENDMENT 1: Clarifications for test methodologies, labelling, and sampling schedule

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

Amendement 1: Éclaircissements pour les méthodologies d'essai, le marquage et le plan d'échantillonnage

Reference number
ISO 7199:2009/Amd.1:2012(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

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.

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.

Amendment 1 to ISO 7199:2009 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*.

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

AMENDMENT 1: Clarifications for test methodologies, labelling, and sampling schedule

Page 2, 3.11

Revise so that it reads:

3.11
residual blood volume
difference between the priming volume of the unit and the blood volume that can be extracted

Page 5, 5.3.1.2

Replace the text with the following:

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 or flow is specified, the test shall be performed at 40 kPa for 6 h or as long as is specified by the manufacturer for clinical use. Visually inspect the device for leakage of water.

Add 5.3.3.3 to read:

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.

Page 8, Table 2

Revise the table as follows:

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:		X	X	X	X
pCO_2					
pO_2					
pH					
Base excess					
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

Page 9, 6.2.1

Revise NOTE 1 so that it reads:

NOTE 1 The symbol ⚠ may be used.

Revise NOTE 2 so that it reads:

NOTE 2 The symbol ⊗ may be used.

ICS 11.040.40

Price based on 2 pages