INTERNATIONAL STANDARD

ISO 7199

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AMENDMENT 1
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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

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Foreword

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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.

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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.