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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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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*.

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# 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  $1,5\times$  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
<i>p</i> CO <sub>2</sub>					
<i>p</i> O <sub>2</sub>					
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  $\Delta$  may be used.

Revise NOTE 2 so that it reads:

NOTE 2 The symbol  $\otimes$  may be used.