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AMENDMENT 1
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Cardiovascular implants and extracorporeal systems — Centrifugal blood pumps

AMENDMENT 1: Worst-case conditions for testing

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Implants cardiovasculaires et systèmes extracorporels — Pompes sanguines centrifuges

AMENDEMENT 1

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Cardiovascular implants and extracorporeal systems — Centrifugal blood pumps

AMENDMENT 1: Worst-case conditions for testing

Clause 3

Add the following term at the end of Clause 3:

3.10
worst-case condition
operating variable within those specified by the manufacturer for intended clinical use which represent the appropriate worst-case device operation for the respective test such as blood cell damage, bearing wear, backflow and cavitation

Clause 4

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Replace the entire subclause of 4.3.3 with the following text:

4.3.3 Pump durability

When determined in accordance with 5.4.3, the components of the pump shall remain functional over the duration of the testing specified by the manufacturer (e.g. bearing durability).

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Add the following subclauses after 4.3.4:

4.3.5 Backflow under pulsatile mode

When tested in accordance with 5.4.5, test results shall demonstrate that no backflow can occur under any conditions in pulsatile mode during the intended clinical use.

4.3.6 Cavitation

When tested in accordance with 5.4.6, test results shall demonstrate that no cavitation can occur during intended clinical use.

5.4.1.2

Add the following text at the end of the subclause:

For rotational blood pumps with an intended use in pulsatile mode, measure the mean pressure differential between the inlet and outlet and the corresponding mean flow rate. Construct a plot showing the mean pressure differential versus mean flow rate for multiple mean r/min settings over the entire rated operating range of the pump for at least three typical intended combinations of frequency and flow amplitude of the pulsatile mode.

To characterize the dynamic pulsatile performance of the blood pump, measure the time-dependent inlet and outlet pressures and the corresponding instantaneous flow rates for at least the minimum and maximum operating conditions over 10 pumping cycles.

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5.4.2.2 Procedure

Replace the text of 5.4.2.2 with the following text:

The worst-case condition for blood cell damage shall be identified for both non-pulsatile and pulsatile modes (if applicable). Justify the choice, taking into account: pressure differential, afterload, flow rate, r/min, amplitude, and frequency as per the operational ranges specified by the manufacturer or based on risk assessment. Blood cell damage tests shall be performed under these identified worst-case conditions.

NOTE Worst-case condition usually occurs at the maximum flow rate for assessing plasma-free haemoglobin levels but can occur at the minimum flow rate in some cases.

Two sets of appropriate circuit components (including a pump in the test circuit and a predicate pump in the control circuit), connecting tubing, and a reservoir (as specified by the manufacturer and of suitable size relative to the device under test) shall be assembled. Priming and de-bubbling of the circuits by recirculating with an appropriate solution is recommended before blood is added. The test liquid volumes shall, at the initiation of the test, be within 3 % of each other. The total circuit volume should be chosen to optimize test sensitivity and system noise and shall not exceed 1 l without appropriate justification. All changes in circuit volume during the test shall be documented (e.g. sampling volume and extra fluid added). A sufficient number of paired tests (e.g. usually 5) should be performed to support a statistical analysis of the blood cell damage results between the pump under test and the predicate pump. The predicate pump should be tested under the same conditions regarding flow rate, preload and afterload using the same blood pool.

The sampling schedule shall be in accordance with Table 2. More frequent sampling times are optional. Test duration shall be 6 h.

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Table 1

Replace Table 1 with the following table:

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

Item	Level	Maximum variation
Pressure differential Afterload Flow rate r/min Amplitude Frequency	Identified and justified worst-case conditions	±5 %
Base	0[a]	±5 mmol/l
Blood glucose	10 mmol/l	±5 mmol/l
Haemoglobin	12 g/dl	±1 g/dl

[a] Zero refers to 24 mmol/l of bicarbonate (HCO_3^-).

Table 2

Replace Table 2 with the following table:

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Table 2 — Sampling schedule

Parameter	Baseline, 0 min	Time after initiation of test min				
		30	90	180	270	360
Plasma free haemoglobin	X	X	X	X	X	X
White blood cells	X	X		X		X
Platelets	X	X		X		X
Blood gas values pH Base		X		X		X
Haemoglobin/haematocrit	X	X		X		X
Glucose	X					
Activated clotting time	X	X	X	X	X	X
Temperature	X	X	X	X	X	X
Flow rates	X	X	X	X	X	X
r/min	X	X	X	X	X	X
Pressure (inflow and outflow)	X	X	X	X	X	X
Circuit volume changes	X	X	X	X	X	X

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5.4.3.2 Procedure

Replace the text of 5.4.3.2 with the following text:

The worst-case conditions for pump durability shall be identified for both non-pulsatile and pulsatile modes (if applicable). Justify the choice, taking into account pressure differential, afterload, flow rate, r/min, bearing forces, amplitude, and frequency. Pump durability tests shall be performed under these identified worst-case conditions for both non-pulsatile and pulsatile modes, respectively. Operate the pump for a minimum of 6 h or at least the maximum operating time as specified by the manufacturer's instructions for use, and measure the flow output of the pump, pressure differential and the r/min for the duration of the test. Assess the extent of wear on the pump components after termination of the test.

NOTE Some regional requirements specify testing to twice the maximum operating time as specified by the manufacturer.

Clause 5

Add the following subclauses after 5.4.4:

5.4.5 Backflow in pulsatile mode

5.4.5.1 Test liquid

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

5.4.5.2 Procedure

The worst-case conditions for backflow shall be identified for pulsatile mode. Justify the choice, taking into account pressure differential, flow rate, r/min, amplitude and a constant (not flow/resistance induced) afterload of at least 20 kPa (150 mm·Hg). Backflow tests shall be performed at the identified worst-case condition using continuous flow. Assess the net flow rate through the pump.

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5.4.6 Cavitation

5.4.6.1 Test liquid

The test liquid shall be a blood analogue.

5.4.6.2 Procedure

The worst-case conditions for cavitation shall be identified. Justify the choice, taking into account: pressure differential, partial pressure of gases, flow rate, r/min, amplitude, frequency, temperature and a constant (not flow/resistance induced) afterload of at least 20 kPa (150 mm·Hg). Cavitation tests shall be performed under these identified worst-case conditions. Assess the occurrence of cavitation, e.g. by means of high-speed video.

6.4

Add the following list items at the end of 6.4:

e) frequency limitations (if applicable);

f) amplitude limitations (if applicable).

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