International Standard

ISO 5840-1

Cardiovascular implants — Cardiac valve prostheses —

Part 1: General requirements

AMENDMENT 1

Implants cardiovasculaires — Prothèses valvulaires —

Partie 1: Exigences générales

AMENDEMENT 1

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Cardiovascular implants — Cardiac valve prostheses —

Part 1: General requirements

AMENDMENT 1

Clause 3, Terms and definitions
3.1

Replace the definition in the term entry as follows:

3.1
accessory

device-specific tool that is required to assist in the implantation and/or adjustment of the *heart valve substitute* (3.30), excluding the delivery system

3.2

Replace the term entry with the following:

3.2
adverse event
AE

untoward medical occurrence, disease or injury, or clinical signs (including abnormal laboratory findings) in patients, whether or not related to the investigational medical device and whether anticipated or unanticipated

Note 1 to entry: For users or other persons, this definition is restricted to events related to the use of investigational medical devices or comparators, whether anticipated or unanticipated.
Note 2 to entry: This definition includes events related to the investigational medical device or the comparator, when applicable.
Note 3 to entry: This definition includes events related to the procedures involved.

3.49

Replace the definition in the term entry as follows:

3.49
regurgitant volume

volume of fluid that flows through and around a *heart valve substitute* (3.30) in the reverse direction during one *cycle* (3.13) and is the sum of the *closing volume* (3.9) and the *leakage volume* (3.35)

Note 1 to entry Clinically, it can only be possible to measure the leakage volume and does not always include the closing volume.

Note 2 to entry See Figure 2.

7.2.2.2, Table 3

Replace the entire table with the following:

	Aortic peak systolic pressure	Aortic end diastolic pressure	Differential pressure across closed valve[b]	
			Aortic	Mitral
	mmHg	mmHg	mmHg	mmHg
normotensive[a]	120	80	100	120
hypotensive	60	40	50	60
mild hypertensive	150	95	125	150
moderate hypertensive	170	105	140	170
severe hypertensive	195	115	155	195
very severe hypertensive	210	120	165	210

[a] For in vitro hydrodynamic minimum performance device testing (i.e. Table 1 and Table 2 of ISO 5840-2:2021 and ISO 5840-3:2021), the aortic peak systolic pressure and aortic end diastolic pressure shall be the control pressures.

[b] With durability testing, the “differential pressure across closed valve” shall define the differential pressure condition that shall be maintained for at least 5 % of the cycle.

7.2.2.2, Table 4

Replace the entire table with the following:

	Pulmonary artery peak systolic pressure	Pulmonary artery end diastolic pressure	Differential pressure across closed valve[a]	
			Pulmonary	Tricuspid
	mmHg	mmHg	mmHg	mmHg
normotensive	25	10	20	25
hypotensive	15	5	10	15
mild hypertensive	45	17	30	45
moderate hypertensive	55	22	40	55
severe hypertensive	75	30	50	75
very severe hypertensive	85	35	60	85

[a] With durability testing, the “differential pressure across closed valve” shall define the differential pressure condition that shall be maintained for at least 5 % of the cycle.

Annex E, Table E.2

Replace the entire table with the following: