International Standard

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AMENDMENT 1
2025-03

Cardiovascular implants — Cardiac valve prostheses —

Part 2: Surgically implanted heart valve substitutes

AMENDMENT 1

Implants cardiovasculaires — Prothèses valvulaires —

Partie 2: Prothèses valvulaires implantées chirurgicalement

AMENDEMENT 1

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This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 285, *Non-active surgical implants,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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Cardiovascular implants — Cardiac valve prostheses —

Part 2: Surgically implanted heart valve substitutes

AMENDMENT 1

Clause 2, Normative references

Add the following reference:

ISO/PAS 7020:2023, *Sizing parameters of surgical valve prostheses: Requirements regarding the application of ISO 5840-2*

Clause 3, Terms and definitions

3.5

Remove Note 2 to entry.

3.6

Remove Note 2 to entry.

3.8

Replace the term "supra-annulus" with "supra-annular region".

3.8
supra-annular region
region wholly above the patient's annulus

Note 1 to entry: See Figure 1.

Note 2 to entry: See also 3.4, 3.5, and 3.7.

6.3.3

Replace the entire subclause with the following text.

Refer to ISO 5840-1:2021, 6.3.4.

Refer to ISO/PAS 7020:2023 for requirements pertaining to labelling of surgical valves.

Annex D contains a list of terms that can be used to describe various valve models.

F.2.1.1

Replace the entire subclause with the following text.

Each pressure measurement (e.g. ventricular pressure, aortic pressure) should have an upper frequency limit (–3 dB cut-off) of at least 30 Hz and a measurement accuracy of at least ±0,26 kPa (±2 mmHg). The flow meter should have an upper frequency limit (–3 dB cut-off) of at least 30 Hz.

Annex F, Table F.2

Replace the entire table with the following:

Beat rate cycles/min	**Systolic duration** %	**Cardiac output** l/min	**Differential pressure across closed valve**[a]
45	30	5	Hypotensive, normotensive, severe hypertensive
70	35	5	Hypotensive, normotensive, severe hypertensive
120	50	5	Hypotensive, normotensive, severe hypertensive
[a] Refers to the mean differential pressure across the closed valve.			

F.2.3.4

Replace the list item g) with the following:

g) regurgitant volume, including the closing volume and leakage volume (see ISO 5840-1:2021, Figure 2), expressed in millilitres and as a percentage of forward flow volume, and the corresponding differential pressure across closed valve (i.e. mean back pressure).