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# 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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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 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:

| Paediatric subpopulation | Systolic duration<br>% | MAP<br>mmHg | Beat rate[a]<br>bpm | Cardiac output[a]<br>l/min |
|---|---|---|---|---|
| newborn | 50 | 45 | 60; 150; 200 | 0,3; 0,5; 1; 1,5 |
| infant | 50 | 55 | 60; 120; 200 | 0,5; 1; 2; 3 |
| toddler | 45 | 65 | 60; 100; 160 | 1,5; 3; 4,5 |
| child | 40 | 80 | 60; 80; 140 | 2; 3,5; 5 |
| adolescent | 35 | 100 | 45; 70; 120 | 2; 5; 7 |
| [a] See Reference [35]. | | | | |

*Annex E, Table E.3*

Replace the entire table with the following:

| Paediatric subpopulation | Systolic duration<br>% | MAP<br>mmHg | Beat rate[a]<br>bpm | Cardiac output[a]<br>l/min |
|---|---|---|---|---|
| newborn | 50 | 20 | 60; 150; 200 | 0,3; 0,5; 1; 1,5 |
| infant | 50 | 20 | 60; 120; 200 | 0,5; 1; 2; 3 |
| toddler | 45 | 20 | 60; 100; 160 | 1,5; 3; 4,5 |
| child | 40 | 20 | 60; 80; 140 | 2; 3,5; 5 |
| adolescent | 35 | 20 | 45; 70; 120 | 2; 5; 7 |
| [a] See Reference [35]. | | | | |

*Annex E, Table E.4*

Replace the entire table with the following:

| Paediatric subpopulation | Steady back pressure[a]<br>mmHg | Steady forward flow rates[a]<br>l/min |
|---|---|---|
| newborn | 40; 80 | 1,5; 3; 5; 10 |
| infant | 40; 80; 120 | 3; 5; 10; 15 |
| toddler | 40; 80; 120 | 5; 10; 15; 20 |
| child | 40; 80; 120; 160 | 5; 10; 15; 20; 25 |
| adolescent | 40; 80; 120; 160; 200 | 5; 10; 15; 20; 25; 30 |
| [a] See Reference [35]. | | |

*Annex E, Table E.5*

Replace the entire table with the following:

| Paediatric subpopulation | Steady back pressure[a]<br>mmHg | Steady forward flow rates[a]<br>l/min |
|---|---|---|
| newborn | 5; 10; 20 | 1,5; 3; 5; 10 |
| infant | 5; 10; 20 | 3; 5; 10; 15 |
| toddler | 5; 10; 20 | 5; 10; 15; 20 |
| child | 5; 10; 20; 30 | 5; 10; 15; 20; 25 |
| adolescent | 5; 10; 20; 30; 40 | 5; 10; 15; 20; 25; 30 |
| [a] See Reference [35] | | |

*Annex H*

Replace the title of Figure H.2 with the following:

Figure H.2 — Example of imaging planes (axial view) for symmetric tri-leaflet (left) and a symmetric bi-leaflet design (right) valve

*I.2.2.2*

Replace the entire subclause with the following text.

A simplified valve test fixture can be used rather than the aortic and mitral transcatheter valve test fixtures as prescribed in ISO 5840-3:2021, Annex C.

*I.2.2.7*

Replace the Note with the following:

NOTE Figure I.2 reference data was obtained using physiological saline with specific gravity of 1,005 g/ml and viscosity of 1,0 cP.

*I.2.3*

Replace the entire subclause with the following text.

The pressure difference across the test valve and the standard nozzle shall be measured over a flow rate range of 5 l/min to 30 l/min in 5 l/min increments. At least five measurements at each flow rate shall be collected.

*I.3.2.3*

Replace the entire subclause with the following text.

For transcatheter valves, the heart valve substitute should be deployed within simplified fixturing/simulated conduits representative of the intended implant site and nominal deployed device diameters. For ViV and ViR indications, the heart valve substitute should be deployed into simulated operating configurations representative of the intended pre-existing prosthetic device.

*I.3.2.4*

Replace the Note with the following:

NOTE Figure I.4 reference data was obtained using physiological saline with specific gravity of 1,005 g/ml and viscosity of 1,0 cP.

*I.3.3*

Replace the entire subclause with the following text.

The leakage across the test valve and the standard nozzle shall be measured at five equidistant back pressures appropriate for the intended device application in accordance with Tables 3 and 4. At least