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Indian Standard

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शल्य चिकित्सा द्वारा कपाटिका प्रत्यारोपण के लिए परिमाण मापदण्ड: ISO 5840-2 के आवेदन सन्दर्भ में अपेक्षाएँ

Sizing Parameters of Surgical Valve Prostheses: Requirements Regarding the Application of ISO 5840-2

ICS 11.040.40

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Medical and Surgical Cardiology Equipment Sectional Committee, MHD 06

NATIONAL FOREWORD

This Indian Standard which is identical to ISO/PAS 7020 : 2023 'Sizing parameters of surgical valve prostheses: Requirements regarding the application of ISO 5840-2' issued by the International Organization for Standardization (ISO) was adopted by the Bureau of Indian Standards on the recommendation of the Medical and Surgical Cardiology Equipment Sectional Committee and after approval of the Medical Equipment and Hospital Planning Division Council.

The document is devised to cater for the inconsistencies with the labeling and instruction for use associated with sizing procedures for heart valve replacement. For aortic valve replacements, severe mismatch may lead to significant risk of mortality and morbidity. The best approach to avoid prosthesis-patient mismatch is prevention. This requires the surgeon to have clear and accurate information about the sizing parameters and effective orifice area of valve being substituted. The document recommends additional valve sizing parameters to be added on the device labeling. The document also presents suitable methods to obtain these parameters and the degree of accuracy required.

The text of ISO standard has been approved as suitable for publication as an Indian Standards without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'; and

b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards, which are to be substituted in their respective places, are listed below along with their degree of equivalence for the editions indicated:

International Standards	*Corresponding Standards*	*Degree of Equivalence*
ISO 5840-1 : 2021 Cardiovascular implants — Cardiac valve prostheses — Part 1: General requirements	IS 17840 (Part 1) : 2022/ISO 5840-1 : 2021 Cardiovascular implants cardiac valve prostheses: Part 1 General requirements	Identical
ISO 5840-2 : 2021 Cardiovascular implants — Cardiac valve prostheses — Part 2: Surgically implanted heart valve substitute	IS 17840 (Part 2) : 2022/ISO 5840-2 : 2021 Cardiovascular implants cardiac valve prostheses: Part 2 Surgically implanted heart valve substitute	Identical

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Introduction

0.1 General

In the past, inconsistencies have been reported with the labelling and instructions for use associated with sizing parameters and sizing procedures for surgical replacement heart valves, specifically, mechanical and stented bioprosthetic valves. These inconsistencies have led to confusion among some users about which size valve to implant in a particular patient and have also led to challenges in comparing results (published or otherwise) from one valve model to another. A solution to the problem can be achieved by providing more complete and accurate sizing information to the clinicians, which will ultimately benefit the patients.

ISO 5840-2 identifies a number of sizing parameters that are required in the labelling (including on the unit box, see ISO 5840-2:2021, 6.3.3, and instructions for use) to inform the selection of a surgical heart valve prosthesis to be implanted in a specific patient. However, no guidance is offered in ISO 5840-2 on how these parameters should be obtained.

0.2 Clinical rationale for additional sizing information

Successful valve replacement therapy requires that an adequate size surgical heart valve substitute is used, based on patient body size and the native valve annulus size. An understanding of valve sizing parameters and appropriate choice of size is critical to post-procedure success since a valve substitute that is too small for the patient can result in prosthesis-patient mismatch. For aortic valve replacements, severe mismatch has been reported in 5 % to 15 % of patients.[1] Severe prosthesis-patient mismatch leads to increased early, mid-term and late mortality, especially if the left ventricular ejection fraction (LVEF) is reduced.[2]-[5] In the mid-term, it causes a higher incidence of heart failure[5] and limits left ventricular mass regression.[5] In the long term, it can also contribute to accelerated structural valve degeneration (SVD).[6] Patients with severe prosthesis-patient mismatch can require replacement of the valve substitute with another having a larger effective orifice area (EOA). However, re-intervention has significant risk of mortality and morbidity.

The best approach to prosthesis-patient mismatch is prevention. This requires the surgeon to have clear and accurate information about the sizing parameters and EOA of each valve substitute.

A surgical heart valve substitute is described by a labelled size given by the manufacturer, which is assumed to be broadly consistent with the size of the patient native valve annulus for which the valve is intended. Literature reviews[1] and studies of haemodynamic function commonly compare valve substitutes by labelled size, but there can be major differences between the patient native valve annulus diameter and the labelled size of the valve substitute.[8]-[11] Intraoperative sizing is further complicated by the need for aortic supra-annular valves to fit within the aortic sinus. The disparity between labelled size and actual size means that echocardiographic or clinical comparisons based on labelled size can be misleading.

The issue of valve sizing is a complex problem and is being addressed in a stepwise fashion. The working group revising ISO 5840-2 proposed a first step toward greater transparency by requiring additional information be added to the unit box, namely, internal orifice diameter and effective orifice diameter. Although this information does not necessarily inform the surgeon on whether the valve would fit in the patient's annulus, it helps to estimate the internal orifice available for blood flow and thus indirectly the EOA. It is not feasible to use clinically measured EOA's since sizing information must be available before a surgical heart valve substitute is released for use in patients. Indeed, it can take a number of years to gather sufficient echocardiographic data to confirm the clinical EOAs. Furthermore, the use of echocardiographic data to help avoid prosthesis-patient mismatch has been criticized because of variability in the measurements obtained in vivo.[12] In vitro steady flow data have less variability and allow meaningful comparison of every design and size of surgical heart valve substitute under the same flow conditions. This information can be used by the surgeon to choose a specific valve substitute type and size based on more standardized parameters than labelled valve size. It is anticipated that further steps toward a standardised approach to sizing will be addressed in subsequent editions of ISO 5840-2.

This document provides further specifications to explain these two parameters (i.e. internal orifice diameter and effective orifice diameter) and other sizing parameters. This document also guides the manufacturer in selecting reproducible methods to obtain these parameters and the degree of accuracy required.

Indian Standard

SIZING PARAMETERS OF SURGICAL VALVE PROSTHESES: REQUIREMENTS REGARDING THE APPLICATION OF ISO 5840-2

1 Scope

This document describes in vitro methods of measurement of the sizing parameters for surgical valves (referring to mechanical and stented bioprosthetic valves only here and hereafter). It represents a consensus reached among manufacturers, independent bioengineers and clinicians, and is underpinned by interlaboratory studies.

This document relates to surgical heart valve prostheses and is intended to be used in conjunction with ISO 5840-1:2021 and ISO 5840-2:2021. Where noted, the requirements of this document clarify certain requirements of ISO 5840-1 and/or ISO 5840-2. Specific methodologies are included for flexible leaflet (bioprosthetic) and rigid (mechanical) valves. Sutureless valves, stentless valves and valved conduits are not included.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 5840-1:2021, *Cardiovascular implants — Cardiac valve prostheses — Part 1: General requirements*

ISO 5840-2:2021, *Cardiovascular implants — Cardiac valve prostheses — Part 2: Surgically implanted heart valve substitutes*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
effective orifice area
EOA
A_{eo}
orifice area that has been derived from flow and pressure or velocity data

Note 1 to entry: For in vitro testing, EOA is defined as:

$$A_{eo} = \frac{q_{V_{RMS}}}{51{,}6\sqrt{\frac{\Delta p}{\rho}}}$$

where

A_{eo} is the effective orifice area, expressed in cm^2;

$q_{V_{RMS}}$ is the root mean square forward flow, expressed in ml/s, during the positive differential pressure period;

Δp is the mean pressure difference, expressed in mmHg;

ρ is the density of the test fluid, expressed in g/cm^3.

3.2
external sewing ring diameter
ESRD
OD-SEWINGRING
outside diameter of the sewing ring at the largest point

Note 1 to entry: The external sewing ring diameter is expressed in millimetres.

Note 2 to entry: See Figure 1.

3.3
heart valve substitute
device used to replace the function of a native valve of the heart

3.4
inflow orifice diameter
ID-INFLOW
inflow internal orifice diameter
<flexible surgical heart valve> orifice diameter measured at inflow with a validated procedure

Note 1 to entry: See Figure 1.

Note 2 to entry: This definition clarifies the definition ISO 5840-2:2021, 3.5 for prosthesis minimum internal diameter for a flexible surgical heart valve.

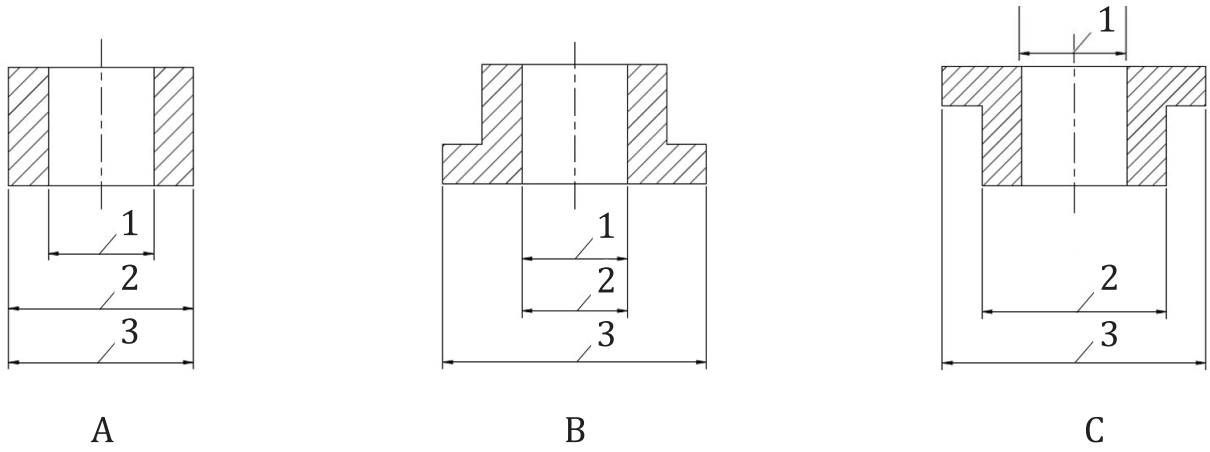
3.5
inflow orifice diameter
ID-INFLOW
inflow internal orifice diameter
<rigid surgical heart valve> inner diameter of the valve housing

Note 1 to entry: See Figure 1.

Note 2 to entry: This definition clarifies the definition ISO 5840-2:2021, 3.6 for prosthesis minimum internal diameter for a rigid surgical heart valve.

3.6
intra-annular
wholly or partially within the patient's annulus

Note 1 to entry: See Figure 1.



Key

1 inflow orifice diameter
2 patient annulus diameter
3 external sewing ring diameter
A aortic/pulmonic intra-annular
B aortic/pulmonic supra-annular
C mitral/tricuspid intra-annular

NOTE This figure is a clarification of ISO 5840-2:2021, Figure 1.

Figure 1 — Designation of dimensions of surgical heart valve substitute sewing ring configurations

3.7
occluder
leaflet component that inhibits backflow

3.8
patient annulus diameter
PAD
diameter of the smallest flow area within the patient's valve annulus

Note 1 to entry: PAD is expressed in millimetres.

Note 2 to entry: See Figure 1.

3.9
effective orifice diameter
ID-EFFECTIVE
D_{eff}
prosthesis minimum internal diameter
diameter derived from hydrodynamic performance data measured with a standard validated procedure

Note 1 to entry: This definition clarifies the definition ISO 5840-2:2021, 3.5 for prosthesis minimum internal diameter.

Note 2 to entry: The effective orifice diameter, D_{eff}, is calculated from EOA data as

$$D_{eff} = 2\sqrt{\frac{A_{eo}}{\pi}}$$

where A_{eo} is the EOA derived from the steady flow pressure gradient.

3.10
supra-annular
wholly above the patient's annulus

Note 1 to entry: See Figure 1.

3.11
valve housing external diameter
OD-HOUSING
outer diameter of the structure that houses the prosthetic valve leaflets

3.12
valve size
designated valve size
manufacturer's designation of a surgical heart valve substitute which indicates the intended patient annulus diameter

Note 1 to entry: The valve size equals to the *patient annulus diameter* (3.9).

Note 2 to entry: This takes into consideration the manufacturer's recommended implant position relative to the annulus and the suture technique.

4 Abbreviated terms

EOA	effective orifice area
ESRD	external sewing ring diameter
ID-INFLOW	inflow orifice diameter
ID-EFFECTIVE	effective orifice diameter
LVEF	left ventricular ejection fraction
OD-HOUSING	outer diameter of housing or valve stent
OD-SEWINGRING	sewing ring external diameter
PAD	patient annulus diameter
SVD	structural valve deterioration

5 Information required for the outer container labelling

5.1 General

ISO 5840-2:2021, 6.3.3 specifies packaging, labelling and sterilization requirements for surgical heart valve prostheses. Most requirements are referenced to ISO 5840-2:2021, 6.3.3. However, ISO 5840-2 includes some additional labelling requirements to appear on the "outer container labelling … in diagrammatic and/or tabular form." The additional items required are:

— intended valve to be replaced;

— intended position in relation to the annulus;

— inflow orifice diameter (see 3.4 and 3.5);

— effective orifice diameter (see 3.9);

— external sewing ring diameter (see 3.2).

This document was conceived to provide clarification and further guidance on the requirements from and application of ISO 5840-2:2021, 6.3.3 using information that was not available when ISO 5840-2 was developed. As a result, the items required to be on the outer container labelling are:

— intended valve to be replaced;

— inflow orifice diameter;

— effective orifice diameter;

— valve housing external diameter;

— external sewing ring diameter.

These requirements shall only apply to mechanical heart valves and stented bioprosthetic valves. These requirements shall not apply to stentless bioprosthetic valves, sutureless heart valves or valved conduits (i.e. valves containing an integrated tubular conduit for reconstruction).

The following subclauses describe how each of these items shall be determined and reported. Valves used for sizing measurements shall represent finished product but do not require any special conditioning (i.e. maximum allowable sterilization, shipping/handling, or storage/aging). Diameters shall be reported to the nearest half millimetre. For example, values of 20,8 mm to 21,2 mm would be reported as 21,0 mm on the labelling, while values of 21,3 mm to 21,7 mm would be reported as 21,5 mm.

5.2 Intended valve to be replaced

The intended valve to be replaced shall be reported as the valve position in which the valve is intended for use (i.e. aortic, mitral, tricuspid or pulmonic). If the valve is intended for use in multiple locations (e.g. aortic and pulmonic), both locations shall be reported.

5.3 Inflow orifice diameter

5.3.1 General

The inflow orifice diameter is a geometric dimension that conveys the size of the valve inflow. Since most surgical valves have a circular orifice, the methods in 5.3 are based on determining one single diameter. It is possible that additional dimensions are required for valves with an intentionally non-circular design.

5.3.2 Mechanical valves

For a mechanical heart valve, the inflow orifice diameter shall be the inner diameter of the valve housing and can be directly measured using a validated method (e.g. micrometer, vision system). In cases where the valve housing is not entirely circular (e.g. flat regions for the hinge features of the occluders), the diameter reported shall be the circular diameter of the housing, not accounting for small non-circular regions.

A minimum of three valves shall be measured per valve size. If the measured diameter is based on fitting a circle constructed from selected points around the inflow inner surface of the valve, a minimum of eight approximately equidistant points shall be used to define the circle. The measured diameter of each valve shall be recorded to 0,1 mm, and the resulting average diameter of all valves measured shall be reported to the nearest half millimetre on the labelling (see 5.1).

5.3.3 Stented bioprosthetic valves

5.3.3.1 General

For a stented bioprosthetic valve, the inflow orifice diameter shall be the inner diameter measured at the inflow of the valve. The following subclauses present two potential methods to measure the inflow orifice diameter for stented bioprosthetic valve. However, the manufacturer can use another method as long as a validation is provided, along with a justification explaining how the method is appropriate for determining this diameter.

5.3.3.2 Conical gauge method

This method involves the use of a conical gauge placed inside the valve to determine the inflow orifice diameter.

To standardize the method, the conical gauge shall meet the following requirements:

— cone material is steel;

— capable of reading diameters in 0,1 mm increments over a range of 15 mm to 30 mm;

— mass of the entire cone is 630 g ± 30 g;

— cone taper angle is 5,7° ± 0,2°;

— smooth surface to minimize friction.

An example of a commercially-available conical plug gauge that meets these requirements is the conical plug gauge 909.492 of Schut Geometrical Metrology[1)] – however, any conical gauge that meets the listed requirements can be used.

Measurements made in air at ambient temperature shall be acceptable for determining the diameter. To reduce friction, and to prevent the possibility of tissue shrinkage due to drying, both the valve and gauge shall be kept wet throughout the procedure by spraying with 0,9 % saline solution. Alternatively, the manufacturer may choose to perform the measurements in saline instead of air or to measure at body temperature instead of ambient conditions (e.g. if the valve stent is manufactured from a temperature-dependent material such as nitinol).

The valve shall be placed on a fixture such that the flow axis of the valve is vertical and the valve inflow is facing upwards. A simple fixture can be a rigid support with a circular hole that allows the valve stent to pass through the hole while the valve sewing ring rests on the support. Depending on the design of the sewing ring, it can be necessary to use some type of fixation method (e.g. clamping, sewing) to secure the valve to the fixture.

The cone gauge shall be slowly lowered into the valve inflow and advanced until it begins to make contact with the valve orifice, with the user being careful to avoid forcing the gauge into the valve. As the gauge makes contact, the user shall carefully release the gauge until it comes to rest under its own weight. The fixture shall allow room above and below the valve for the conical gauge to rest inside the valve without tipping the fixture over or contacting other materials. A stand may be used for alignment purposes only but should not support the weight of the gauge.

The gauge shall be allowed to settle within the tissue valve for approximately 10 s before reading the diameter from the gauge. The reading shall be taken at the base of the stent. The diameter value on the gauge shall be checked at different equidistant points to look for gross misalignment of the gauge relative to the flow axis, in which case the procedure shall be repeated. If the inlet of the valve has a “scalloped” shape, the largest diameter reading (i.e. the most inflow edge of the scalloped stent) shall be recorded.

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1) The conical plug gauge 909.492 of Schut Geometrical Metrology is an example of a suitable product available commercially. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of this product.

A minimum of three valves shall be measured per valve size. Each valve shall be measured no more than three times as a conditioning step, then each valve shall be measured a total of five times. The gauge shall be removed and repositioned between repeated measurements. Diameters shall be recorded to 0,1 mm in each reading. The results from the last five measurements, but not the initial conditioning measurements, shall be used during data analysis. The resulting average diameter of all valves tested shall be reported to the nearest half millimetre on the labelling (see 5.1).

The manufacturer shall perform a validation of the measurement system to understand repeatability and reproducibility.

5.3.3.3 Other methods

The inflow orifice diameter may also be measured by other methods validated by the manufacturer, such as optical methods (e.g. optical comparator, vision systems) or contact-based methods.

The measurement locations shall represent the inner surface of the region available to flow. For example, this location can represent the inner surface of a covered stent if the leaflet is mounted outside the stent. The manufacturer shall justify the chosen method and how the measurement locations selected represent the inflow orifice diameter.

A minimum of three valves shall be measured per valve size. If the measured diameter is based on fitting a circle constructed from selected points around the inflow inner surface of the valve, a minimum of eight approximately equidistant points shall be used to define the circle. The measured diameter of each valve shall be recorded to 0,1 mm, and the resulting average diameter of all valves measured shall be reported to the nearest half millimetre on the labelling (see 5.1).

5.4 Effective orifice diameter

5.4.1 General

The effective orifice diameter conveys the effective (or net) cross-sectional area available for flow. It is not a physical geometric dimension, but a hydraulic performance metric. This effective orifice diameter shall be determined using steady flow testing as described in 5.4.2. On the labelling, diameters shall be reported to the nearest half millimetre (see 5.1).

5.4.2 Steady flow method

This method involves using steady forward flow testing to determine the effective orifice area and calculating an effective orifice diameter from the results. This same method can be applied to both mechanical heart valve prostheses and stented bioprosthetic valves.

Basic details regarding the methodology for steady forward flow testing can be taken from ISO 5840-1:2021, Annex I. Details from from ISO 5840-1:2021, Annex I that are not included here remain as recommendations. Steady forward flow testing performed in accordance with this document may be used to meet the expectations of steady forward flow testing per ISO 5840-2.

Testing shall be conducted in a straight tube with an internal diameter dependent on the valve inflow orifice diameter (as determined per 5.3).

— For valves with an inflow orifice diameter of 20,0 mm or less, testing shall be conducted in a straight tube with a 25 mm internal diameter; if the design of the valve prevents it from fitting in a 25 mm tube, then a 35 mm tube shall be used.

— For valves with an inflow orifice diameter greater than 20,0 mm, testing shall be conducted in a straight tube with a 35 mm internal diameter; if the design of the valve prevents it from fitting in a 35 mm tube, then a larger tube shall be used and a rationale provided.

The test system shall be capable of generating flow rates over a minimum of five to a maximum of 30 l/min. Pressure taps shall be located one tube internal diameter upstream and three tube internal

diameters downstream from the annular plane of the heart valve substitute. Other pressure tap configurations may be used if sufficient data can be provided to demonstrate comparable results. Pressure taps shall be flush with the inner wall of the tube. For bileaflet mechanical valves, valves shall be oriented with the hinge plane 90° from the axis of the pressure taps.

Differential pressure measurements shall have a measurement accuracy of at least ±0,26 kPa (±2 mmHg). All other measurement equipment should have a measurement accuracy of at least ±5 % of the maximum intended measurement (e.g. if the maximum measured flow rate is to be 30 l/min, then the required minimum flow meter accuracy would be ±1,5 l/min). The test fluid shall be isotonic saline. Testing shall be performed at body temperature.

A standardized nozzle, specified in ISO 5840-1:2021, Figure I.1, shall be used to characterize the pressure and flow measuring equipment by comparing the measured and expected values for the pressure gradients as a function of flow rate, provided in ISO 5840-1:2021, Figure I.2.

A minimum of three valves per valve size shall be tested over a range of flow rates from 5 l/min to 30 l/min in increments of 5 l/min. The data for pressure gradient as a function of flow rate shall be plotted and reported.

Using the pressure gradient at a flow rate of 25 l/min, the effective orifice area shall be calculated per the Gorlin formula as expressed for steady flow (the formula in 3.1 is expressed for pulsatile flow):

$$A_{eo} = \frac{Q}{51{,}6\sqrt{\frac{\Delta p}{\rho}}}$$

where

A_{eo} is the effective orifice area, expressed in cm^2;

Q is the steady forward flow rate, expressed in ml/s;

Δp is the pressure gradient, expressed in mmHg;

ρ is the density of the test fluid, expressed in g/cm^3;

51,6 is the coefficient that accounts for all required unit conversions (note that the formula result will be incorrect if the wrong units are used).

Assuming a circular orifice, the effective orifice diameter shall then be calculated from the effective orifice area using the formula from 3.9.

The effective orifice diameter of each valve tested shall be calculated to 0,1 mm and the resulting average diameter of all valves tested shall be reported to the nearest half millimetre on the labelling (see 5.1). However, the average effective orifice diameter shall be compared to the inflow orifice diameter determined per 5.4. The effective orifice diameter should not be larger than the physical inflow orifice diameter. Otherwise, if a test error cannot be identified as the cause and corrected, the inflow orifice diameter shall also be reported as the effective orifice diameter on the labelling.

5.5 Valve housing external diameter

The valve housing external diameter shall be measured directly. For valves which have an intra-annular element, the valve housing diameter is the largest external diameter of the portion intended to reside within the annulus. Examples include the pivot guards of a mechanical valve or the cloth-covered stent of a tissue valve in the mitral position. For valves which are intended to be completely supra-annular, the valve housing diameter is the external diameter of the portion holding the prosthetic leaflets. Examples include the cloth-covered housing of a mechanical valve or the cloth-covered stent of a tissue valve.

Manufacturers may use any validated measurement method. One example method is a series of hole gauges in 0,1 mm diameter increments to determine the smallest hole into which the valve housing will fit completely until the sewing ring touches the gauge. This ensures that the largest housing diameter is measured if the housing has a non-circular or non-cylindrical surface. Other methods may include optical methods (e.g. optical comparator, vision systems) or contact-based methods.

A minimum of three valves shall be measured per valve size. If the measured diameter is based on fitting a circle constructed from selected points around the inflow inner surface of the valve, a minimum of eight approximately equidistant points shall be used to define the circle if measuring a cylindrical structure, or a minimum of three points if measuring stent posts. The measured diameter of each valve shall be recorded to 0,1 mm, and the resulting average diameter of all valves measured shall be reported to the nearest half millimetre on the labelling (see 5.1).

5.6 External sewing ring diameter

The external sewing ring diameter shall be measured directly. Manufacturers may use any validated method. Example methods include optical methods (e.g. optical comparator, vision systems) or contact-based methods. However, care should be taken to avoid radially compressing the sewing ring to ensure an accurate measurement.

A minimum of three valves shall be measured per valve size. If the measured diameter is based on fitting a circle constructed from selected points around the inflow inner surface of the valve, a minimum of eight approximately equidistant points shall be used to define the circle. The measured diameter of each valve shall be recorded to 0,1 mm, and the resulting average diameter of all valves measured shall be reported to the nearest half millimetre on the labelling (see 5.1).

6 Labelling format

As summarized in 5.1, certain information is required to appear on the “outer container labelling … in diagrammatic and/or tabular form.” Since the effective orifice diameter is not a physical dimension and thus is not suitable for diagrammatic presentation, a tabular form is recommended for presenting the required information. An example format based on a 21 mm aortic valve appears in Table 1.

Table 1 — Example labelling format

POSITION	AORTIC
ID-INFLOW	21,0 mm
ID-EFFECTIVE	19,5 mm
OD-HOUSING	24,0 mm
OD-SEWING RING	29,0 mm

Information already displayed elsewhere on the labelling, such as the intended valve to be replaced, does not need to be included in this table.

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Amendments Issued Since Publication

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