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Standard Guide for Design Verification Device Size and Sample Size Selection for Endovascular Devices[1]

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1. Scope

1.1 This guide provides guidance for selecting an appropriate device size(s) and determining an appropriate sample size(s) (that is, number of samples) for design verification testing of endovascular devices. A methodology is presented to determine which device size(s) should be selected for testing to verify the device design adequately for each design input requirement (that is, test characteristic). Additionally, different statistical approaches are presented and discussed to help guide the developer to determine and justify sample size(s) for the design input requirement being verified. Alternate methodologies for determining device size selection and sample size selection may be acceptable for design verification.

1.2 This guide applies to physical design verification testing. This guide addresses in-vitro testing; in-vivo/animal studies are outside the scope of this guide. This guide does not directly address design validation; however, the methodologies presented may be applicable to in-vitro design validation testing. Guidance for sampling related to computational simulation (for example, sensitivity analysis and tolerance analysis) is not provided. Guidance for using models, such as design of experiments (DOE), for design verification testing is not provided. This guide does not address sampling across multiple manufacturing lots as this is typically done as process validation. Special considerations are to be given to certain tests such as fatigue (see Practice E739) and shelf life testing (see Section 8).

1.3 Regulatory guidance may exist for endovascular devices that should be considered for design verification device size and sample size selection.

1.4 *Units*—The values stated in SI units are to be regarded as the standard. No other units of measurement are included in this standard.

1.5 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E739 Practice for Statistical Analysis of Linear or Linearized Stress-Life (*S-N*) and Strain-Life (ε-*N*) Fatigue Data

F2914 Guide for Identification of Shelf-life Test Attributes for Endovascular Devices

2.2 *ISO Standards:*[3]

ISO 14971:2012 Medical devices—Application of risk management to medical devices

3. Terminology

3.1 *Definitions:*

3.1.1 *attribute data, n*—data that identify the presence or absence of a characteristic (for example, good/bad or pass/fail).

3.1.2 *design input requirements, n*—physical and performance requirements of a device that are used as a basis for device design (typically defined as test characteristics such as balloon burst pressure, shaft tensile strength, and so forth).

3.1.3 *design output, n*—features of the device (that is, dimensions, materials, and so forth) that define the design and make it capable of achieving design input requirements.

3.1.4 *design subgroup, n*—set defined by the device sizes within the device matrix in which the essential design outputs do not vary for a specified design input requirement (that is, device sizes that share the same design for a specified design input requirement).

3.1.5 *design validation, n*—establishing by objective evidence that the device conforms to defined user needs and intended use(s).

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

3.1.6 *design verification, n*—confirmation by examination and provision of objective evidence that the device design (design output) fulfills the specified requirements (design input).

3.1.7 *device matrix, n*—entire range of available models/sizes for the device family.

3.1.8 *device size, n*—individual model/size (for example, 6 mm diameter by 25 mm length balloon on 135 cm length catheter or a 6Fr 100 cm length guide catheter).

3.1.9 *endovascular device, n*—device used to treat vascular conditions from within the vessel.

3.1.10 *essential design output, EDO, n*—design feature(s) or characteristic(s) of the device that affects its ability to achieve the design input requirements (that is, design output(s) that has a relevant effect on the test results).

3.1.11 *process validation, n*—establishment by objective evidence that a process consistently produces a result or device achieving its predetermined requirements.

3.1.12 *safety factor, n*—ratio of the device performance to the specification requirement (for example, how much stronger the device is than it needs to be to meet its specification requirement).

3.1.13 *sample size, n*—quantity of individual specimens of a device tested.

3.1.14 *variables data, n*—data that measure the numerical magnitude of a characteristic (how good/how bad).

4. Significance and Use

4.1 The purpose of this guide is to provide guidance for selecting appropriate device size(s) and determining appropriate sample size(s) for design verification of endovascular devices. The device size(s) and sample size(s) for each design input requirement should be determined before testing. The device size(s) selected for verification testing should establish that the entire device matrix is able to achieve the design input requirements. If testing is not performed on all device sizes, justification should be provided.

4.2 The sample size justification and statistical procedures used to analyze the data should be based on sound scientific principles and should be suitable for reaching a justifiable conclusion. Insufficient sample size may lead to erroneous conclusions more often than desired.

4.3 Guidance regarding methodologies for determining device size selection and appropriate sample size is provided in Sections 5 and 6.

5. Selection of Device Size(s)

5.1 Design input requirements are the physical and performance requirements of a device that are used as a basis for device design. Once the device design is defined, testing is typically performed to verify that the design input requirements are met. The appropriate device size(s) for verification testing should be determined for each design input requirement. Testing the same device size(s) is typically not appropriate to verify all design input requirements. Differences in the device design throughout the device matrix will drive which device size(s) is selected for verification of each design input requirement.

5.1.1 As explained in subsequent sections, when determining device size(s) for testing, the following should be considered for each design input requirement:

5.1.1.1 Essential design outputs,

5.1.1.2 Design subgroups, and

5.1.1.3 Other considerations.

5.2 *Define Essential Design Outputs (EDOs)*—The design outputs of the device are the features of the device (that is, dimensions, materials, and so forth) that define the design and make it capable of achieving design input requirements. Not all design outputs are essential for each design input requirement. Therefore, for each design input requirement, the essential design outputs (EDOs) should be identified. In Table 1, example EDOs for design input requirements of a balloon catheter device are provided.

5.3 *Define Design Subgroups:*

5.3.1 The design subgroups should be defined for each design input requirement based on the EDOs identified.

5.3.2 For a specific design input requirement, the design subgroups can be defined as one of the following:

5.3.2.1 The entire device matrix if the EDOs for the design input requirement are constant throughout the entire device matrix,

5.3.2.2 Subsets of the device matrix if the EDOs for the design input requirement vary in groups or stages throughout the device matrix, or

5.3.2.3 Each individual device size of the device matrix if EDOs for the design input requirement are different for each individual device size.

5.3.3 Fig. 1 represents the device matrix (entire range of available device sizes) for a 135 cm length balloon catheter device that has balloon diameters ranging from 3 to 7 mm and balloon lengths ranging from 10 to 50 mm. Balloon catheters are available in any combination of balloon diameter and length resulting in 25 unique device sizes in the device matrix.

5.3.4 Figs. 2-4 illustrate how the device matrix in Fig. 1 is defined by different design subgroups for different design input requirements. Fig. 2 represents a design subgroup that is defined by the entire device matrix because all device sizes share the same design for the specified design input requirement (that is, the EDOs remain constant for all device sizes).

TABLE 1 Example EDOs for Design Input Requirements for a Balloon Catheter Device

Design Input Requirement	EDOs
Manifold connection/ Luer lockability	Luer thread dimensions Manifold material
Catheter shaft tensile strength for a single lumen catheter	Shaft material Shaft cross sectional area (diameter and wall thickness) Shaft bond design
Balloon compliance (diameter versus pressure)	Balloon diameter Balloon material Balloon wall thickness
Balloon deflation time	Balloon volume Shaft deflation lumen design

Device Matrix		Balloon Length				
		10 mm	20 mm	30 mm	40 mm	50 mm
Balloon Diameter	3 mm	x	x	x	x	x
	4 mm	x	x	x	x	x
	5 mm	x	x	x	x	x
	6 mm	x	x	x	x	x
	7 mm	x	x	x	x	x

FIG. 1 Device Matrix for a Balloon Catheter Device (25 Unique Device Sizes)

Design Subgroup: EDOs Constant		Balloon Length				
		10 mm	20 mm	30 mm	40 mm	50 mm
Balloon Diameter	3 mm	Manifold/Luer Lock "A"				
	4 mm					
	5 mm					
	6 mm					
	7 mm					

FIG. 2 Design Subgroup for Manifold Connection/Luer Lockability Testing (EDOs Remain Constant throughout the Device Matrix)

The design input requirement is manifold connection/luer lockability testing, and the EDOs (luer thread dimensions and manifold material) are the same for all sizes in the device matrix.

5.3.5 Figs. 3 and 4 represent design subgroups that are subsets of the device matrix because the EDOs for the design input requirement vary throughout the device matrix. Fig. 3 represents design subgroups for shaft tensile strength for a device that contains two different shaft designs in the device matrix, but the other EDOs that were identified (shaft material and shaft bond design) are the same for the entire device matrix. Therefore, there is a design subgroup that is defined by the device sizes that have shaft design "A" and a design subgroup that is defined by the device sizes that have shaft design "B." Fig. 4 represents design subgroups for balloon compliance in which each balloon diameter defines a unique design subgroup.

5.4 *Design Input Requirements and Other Considerations*—In addition to design subgroup definition, design input, device labeling, or regulatory requirements may make it necessary to test additional sizes.

5.5 *Device Size Selection Approach:*

5.5.1 *Approach*—Once the design subgroups are defined for a given design input requirement, the device size(s) to be tested for design verification testing can be appropriately selected by using one of the following approaches:

5.5.1.1 Test each design subgroup,

5.5.1.2 Test the worst-case design subgroup, or

5.5.1.3 Test a subset of the design subgroups.

5.5.2 *Test Each Design Subgroup:*

5.5.2.1 Depending on the design subgroup definition, testing each design subgroup may translate into testing one device size or multiple device sizes to verify the entire device matrix.