PD ISO/TS 17665-3:2013

BSI Standards Publication

Sterilization of health care products — Moist heat

Part 3: Guidance on the designation of a medical device to a product family and processing category for steam sterilization

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National foreword

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Sterilization of health care products — Moist heat —

Part 3: Guidance on the designation of a medical device to a product family and processing category for steam sterilization

Stérilisation des produits de santé — Chaleur humide —

Partie 3: Directives concernant la désignation d'un dispositif médical pour une famille de produits et catégorie de traitement pour la stérilisation à la vapeur

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Foreword

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The committee responsible for this document is ISO/TC 198, *Sterilization of health care products*.

ISO 17665 consists of the following parts, under the general title *Sterilization of health care products — Moist heat*:

— *Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

— *Part 2: Guidance on the application of ISO 17665 Part 1: 2006 [Technical Specification]*

— *Part 3: Guidance on the designation of a medical device to a product family and processing category for steam sterilization [Technical Specification]*

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Introduction

The type of moist heat sterilization process used to successfully process a medical device is identified from the physical, design, material and functional characteristics of the medical device and any sterile barrier system and/or packaging system used to present the medical device for sterilization.

Manufacturers of moist heat sterilizers may supply sterilizers with a number of pre-set sterilization processes. These pre-set sterilization processes may be suitable for sterilizing a wide range of medical devices or combinations of medical devices; however, there may be a need to develop customized sterilization processes to sterilize medical devices or combinations of medical devices that pose a particular challenge to the pre-set sterilization processes.

The designs and nature of materials used to construct medical devices are increasing in complexity. Materials used in the manufacture of sterile barrier systems and/or packaging systems and the combinations of different medical devices in procedure sets can adversely affect conductivity, air removal and moist heat penetration, causing a failure to obtain the required sterility assurance level.

The classification of a medical device into a product family can assist with the development of moist heat sterilization process conditions for this medical device. Assigning a medical device to a particular product family is the first stage of performance qualification at the point of use as specified in ISO 17665-1 and ISO/TS 17665-2. The efficacy of sterilization for a medical device using the sterilization process for that product family should be assessed and documented together with any pre-treatments, such as cleaning, disinfection to reduce bioburden followed by lubrication and humidification of some materials e.g. those containing cellulose.

In this part of ISO 17665 the attributes which relate to efficient sterilization and which are used to identify a product family have been selected from operational experience, engineering considerations and experimental data relating to the efficacy of the different types of moist heat sterilizers and their sterilization processes, and the types and design of differing medical devices and sterile barrier systems and/or packaging systems. Medical devices that are labelled by the manufacturer as being capable of being sterilized via moist heat may be categorized into product families by a user. However, not all medical devices will fit into one of the product families described in this part of ISO 17665. In these cases, new product families will need to be identified based on the consideration of the products attributes and require additional performance qualification.

Medical devices that have been classified into different product families are often processed in the same sterilization load when assembled into a randomly selected load configuration. This approach is common and acceptable in health care facilities where it is generally not feasible to qualify each sterilization load, provided that the sterilization process and sterilizer have been shown to be capable of sterilizing the range of product families constituting the sterilization load. Care should be taken to ensure that the combination of product families does not create a greater sterilization challenge than that set by the individual product families. In addition, consideration should be given to possible adverse interactions between medical devices such as the contamination of instruments with textile fibres. The examples shown in Annex B and D are illustrations of how the coding system is intended to be used in developing a sterilizer load.

This part of ISO 17665 should be read in conjunction with ISO 17665-1 and ISO/TS 17665-2.

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Sterilization of health care products — Moist heat —

Part 3: Guidance on the designation of a medical device to a product family and processing category for steam sterilization

1 Scope

This part of ISO 17665 provides guidance about the attributes of a medical device to be considered by the user when assigning a medical device to a product family for the purpose of identifying and aligning it to a processing category for a specific moist heat sterilization process.

NOTE While this part of ISO 17665 is applicable to health care facilities, it may be used by a manufacturer of a sterile medical device and/or whenever information on reprocessing is required (see ISO 17664).

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 17665-1:2006, *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 17665-1 and the following apply.

3.1
master product
medical device or procedure set used to represent the most difficult to sterilize item in a product family or processing category

3.2
processing category
collection of different products or product families that can be sterilized together

3.3
steam penetration resistance
challenge to a sterilization process from a medical device, including any sterile barrier/packaging system that may delay attainment of the process parameters for moist heat sterilization on all parts of the medical device

3.4
user
responsible body, which can be an individual or group, accountable for ensuring products are sterilized and suitable for intended use

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4 Classification

Each medical device, whether new or modified, should be classified using the general attributes listed in Table 1. Specific characteristics of a medical device should, as applicable, be identified from the subclauses detailed in 4.2.

NOTE 1 Requirements for information to be provided by the manufacturer for the reprocessing of resterilizable medical devices are given in ISO 17664.

If a collection of medical devices are to be contained in a sterile barrier system and/or packaging system e.g. a procedure set, the challenge to the sterilization process from each medical device should be rated relative to the other medical devices as described in this part of ISO 17665. The product family assigned to this collection should be determined by the medical device which presents the greatest challenge to the sterilization process and the sterile barrier system and/or packaging system used. This product family will enable an appropriate processing category and sterilization process to be selected. The combination of the device with the highest rating and the chosen sterilization process should be subject to qualification in accordance with ISO 17665-1.

NOTE 2 Requirements and guidance for sterile barrier systems and packaging systems may be found in ISO 11607 (all parts) and EN 868 (all parts).

Some combinations of physical characteristics, such as those specified in Table 1, may cause an unpredictable adverse change to the steam penetration resistance as illustrated in Table 6. This can lead to an underestimation of the difficulty to sterilize (see Clause 5, Example 2). In such situations performance qualification should always be carried out in accordance with ISO 17665-1.

4.1 General attributes

Table 1 — General attributes

Attribute	Code
Design	a
Weight	b
Material	c
Sterile barrier system	d

4.2 Detailed attributes

The following attributes provide detail for characterizing a medical device and a sterilization process. Increased resistance to steam penetration is indicated by ascending code numbers.

Some attributes will be specified by the manufacturer of the medical device and others by the user. The manufacturer of a medical device will usually specify the attributes needed by the user to assess its steam penetration resistance and to select a processing category for a specific sterilizer and sterilization process. Both the resistance and the category should be reassessed when the medical device is to be combined with others in a sterile barrier system and/or packaging system.

The sterilization process should be qualified to verify that the required lethality will be delivered to all medical devices processed together (see ISO 17665-1 and ISO/TS 17665-2).

4.2.1 Design

For the purpose of identifying a type of sterilization process for reprocessing and assigning a processing category, a medical device should be broadly identified from one or more of the designs described in Table 2. The steam penetration resistance will be different for each design when air is to be removed and replaced by saturated steam. The following should be considered when developing an air removal process.

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a1: air is displaced predictably as temperature rises with the introduction of steam. This action is unlikely to be affected by orientation.

a2: instrument may need to be in an open position and an active air removal process may be necessary.

a3: residual air in hollows may cause unpredictable delays to sterilizing conditions. Defined orientation and/or the dilution of air by an active air removal process may be necessary.

a4: inadequate removal of air during the air removal stage of the sterilization process can cause uncertainty in the attainment of sterilizing conditions.

a5: an active air removal process will be required. Condensate resulting from temperature differences within materials, interaction between adjacent medical devices and the quality of steam can cause an adverse effect on the efficiency of air dilution.

a6: an active air removal process will be required. Condensate can cause occlusion, inadequate air removal and inadequate steam penetration.

a7: if an active air removal process is required, develop the sterilization process to the product.

Table 2 — Design

Structure	Code (a)	Example
Solid, hollow	1	Bowl, jug, dish, bottle, chisel, single piece skin retractor, single component empty instrument tray
Pin and box joints	2	Scissor, forceps, needle holder
Lumen	3	Laparoscopic sheath, sucker, cannulated reamer, rigid endoscope, cannulated screws
Porous	4	Linen, filters, gauze
Tubing, moving parts, tortuous paths	5	Power tool hose, silicone tubing, dental hand piece, ear nose throat drill,
Lumen surrounded by a large mass	6	Drill, cannulated screw driver, obturator, ratchet handle, bored handle
Other	7	Pre-filled syringe

4.2.2 Material

The materials used to manufacture a medical device will be either metallic or non-metallic or a combination of both. Typically, metallic materials will have a high thermal conductivity and non-metals will have low thermal conductivity.

Materials with low thermal conductivity exhibit higher temperature differences throughout the material when compared to materials with high thermal conductivity. Both types of material present challenges to the sterilization process. The moisture content of the material may also influence the heat transfer into the product. This should be taken into account during performance qualification with the material in its most challenging state.

When compared to materials with low thermal conductivity, materials with high thermal conductivity and equal heat capacity will:

— initially generate more condensate in a given time period,

— absorb and release energy faster,

— attain a state of equilibrium faster.

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Examples of some of the materials used are shown in Table 3.

Table 3 — Materials

Material	Example material	Code (b)
Metal	Stainless steel, carbon steel copper and copper-based alloys. Other metals or combinations of metal.	1
Non-metal	Glass, cellulose, polycarbonate, PVC, PTFE, silicon. Other non metals.	2

4.2.3 Weight

The weight of a medical device, or part of a medical device (if processed separately), or for a collection of medical devices grouped into a single sterile barrier system and/or packaging system, should be assigned to one of the codes indicated in Table 4. This information may be required when judging:

— heat-up time;

— cooling time/drying time;

— exposure time in a mixed weight sterilizer load;

— the stability of a single or composite construction material;

— the amount of condensate and its effect on steam penetration.

Table 4 — Weight

Weight g	Code (c)
Less than 50	1
50 to 499	2
500 to 1999	3
2000 and greater	4

4.2.4 Sterile barrier system and/or packaging system

Except when a medical device is to be presented aseptically immediately after being re-processed, it will be contained in a sterile barrier system and/or packaging system prior to it being sterilized [see ISO 11607 (all parts) for code d2 to d4 in Table 5]. When establishing the steam penetration resistance and moisture retention for a medical device or a collection of medical devices, the influence on the combined steam penetration resistance caused by the system and the materials used in its construction should be known. A collection of sterile barrier systems and /or packaging systems are listed in Table 5.

NOTE 1 In some countries local regulations may forbid the sterilization of unwrapped medical devices, in which case code d1 would not apply.

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Table 5 — Sterile barrier system and/or packaging system

Sterile barrier system	Code (d)
None	1
Single wrapped/pouch	2
Double wrapped in wrapping material or pouches, double wrapped container or tray, reusable sterilization container according to manufacturers instructions	3
Combination of two or more systems, for example, a reusable sterilization container with an inner sterile barrier system	4

NOTE 2 Information on the intended use of the sterile barrier systems will be available from the manufacturer. The effect of combining two or more systems (d4) may require additional performance qualification (see ISO 17665-1:2006, Clause 8).

5 Product family (pf)

The product family assigned to a medical device should be based on attributes identified from the ones shown in 4.2. A number of product families that could be established from these attributes are listed in Table 6.

Use Table 6 to assign a product family to a medical device and then from this assignment identify the steam penetration resistance. For each medical device:

— select a level for each attribute a to d;

— establish a match to one of the product families in the table;

— note the product family and then from column 'e', the estimate for steam penetration resistance;

— if a match cannot be obtained, establish a new one and then by comparison with established product families and from performance qualification, estimate a steam penetration resistance.

A discussion and estimate for steam penetration resistance for three types of medical devices are shown in 5.1, 5.2 and 5.3. A user may need to establish additional product families for those designs that cannot be characterized into one of the seven designs illustrated in Table 2.

The steam penetration resistance assigned to each product family listed in Table 6 is estimated and judged from the attributes identified in Clause 4. This estimation is first based on the design of the medical devices in the family and then adjusted if influenced by the other attributes. A procedure set will often contain a range of medical devices and components each assigned a different product family and a different steam penetration resistance. The product family assigned to a procedure set should normally align with the medical device or component assigned the highest steam penetration resistance unless influenced by adjacent medical devices and/or components. Examples are illustrated in Annex B.

The actual steam penetration resistance will depend on the load configuration and any one of the following:

— design of the sterilizer;

— type of operating cycle;

— operational state of the sterilizer witnessed by validation and conformity to the requirements for scheduled periodic tests;

— quality of services delivered to the equipment witnessed by test;

— site.

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5.1 Example 1 — pf 1

A shallow, thin wall, metal bowl.

— design: a1,

— material: b1,

— weight: c1,

— sterile barrier system and/or packaging system: d1.

Steam condensing on the bowl will cause a higher concentration of air on its surfaces. This air will be displaced by steam and sterilizing conditions will exist on its surface when the sterilization temperature is measured at the reference measurement point e.g. the chamber drain.

Nominal changes to the non-condensable gases (NCG) in the steam and/or to air leakage into the sterilizer chamber are unlikely to adversely affect the predicted efficiency of the sterilization process.

The estimated steam penetration resistance for this medical device is e1 (see Table 6) based on design a1. The other attributes of the device will not affect this estimation.

5.2 Example 2 — pf 24

A length of thin wall soft plastic tubing.

— design: a5,

— material: b2,

— weight: c1,

— sterile barrier system and/or packaging system: d3.

Sterilization temperature measured at the reference measurement point may not be indicative of sterilizing conditions within the tubing. The following should be considered when selecting a sterilization process and loading configuration:

— an active air removal system is necessary;

— thin wall tubing is susceptible to kinking and collapse;

— occlusion caused by condensate will prevent the removal of air from within the tube and delay or prevent the presence of sterilizing conditions;

— steam condensing on adjacent items can cause an increase in NCG local to the tube and this gas can then be driven by the steam into the tubing;

— air leakage into the sterilizer chamber and/or increased NCG carried by the steam can add to the air already in the tubing and this can then adversely affect the predicted efficiency of the sterilization process.

The estimated steam penetration resistance according to design a5 will be e5. For this medical device, the other attributes listed in Clause 4 will not affect this estimate.

Providing the above considerations are observed when selecting a sterilization process and loading configuration, the estimated steam penetration resistance should remain at e5. However, due to the number of variables listed above, steam penetration resistance may need to be judged from performance qualification (see ISO 17665-1).

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5.3 Example 3 — pf 27

Cannulated screw driver with a non-metallic or metallic coated handle.

— design: a6,

— material: b2,

— weight: c2,

— sterile barrier system and/or packaging system: d3.

Poor heat transfer through the surface of the handle will delay the presence of sterilizing conditions in the lumen. This delay can vary for most of the reasons given in example 2.

The estimated steam penetration resistance based on design a6 will be e6. Weight and material may affect this estimate.

Table 6 — Product families

MD	**Attribute**																		**Steam penetration resistance** (estimated)							
PF	Design (a)								Material (b)		Weight (c)				Sterile barrier system and/or packaging system (d)				(e)							
	1	2	3	4	5	6	7	+	1	2	1	2	3	4	1	2	3	4	1	2	3	4	5	6	7	+
1	x								x		x	x	x		x				x							
2	x								x					x	x					x						
3	x									x	x	x	x		x					x						
4	x									x				x	x						x					
5	x								x		x	x	x			x				x						
6	x									x	x	x					x	x			x					
7	x									x			x	x		x	x	x				x				
8			x						x		x	x			x	x	x	x			x					
9			x						x				x	x	x	x	x	x				x				
10			x							x	x	x			x						x					
11			x							x	x	x				x	x	x				x				
12			x							x			x	x		x	x	x					x			
13				x						x	x				x	x					x					
14				x						x	x						x	x				x				
15				x						x		x	x	x			x						x			
16		x							x		x				x					x						
17		x							x		x						x	x			x					
18		x								x	x				x					x						
19		x								x	x					x	x	x			x					
20					x				x		x				x							x				
21					x				x		x	x				x	x	x					x			

[a] Special - sterilization process should be developed and qualified.

+ New product families that may be identified by the user.

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Table 6 *(continued)*

MD	**Attribute**																		**Steam penetration resistance** (estimated)							
PF	Design (a)								Material (b)		Weight (c)				Sterile barrier system and/or packaging system (d)				(e)							
	1	2	3	4	5	6	7	+	1	2	1	2	3	4	1	2	3	4	1	2	3	4	5	6	7	+
22					x					x	x	x			x								x			
23					x				x				x	x		x	x	x					x			
24					x					x	x	x				x	x	x					x			
25					x					x			x	x		x	x	x					x			
26						x			x	x			x	x		x	x	x						x		
27						x			x			x	x		x	x	x	x					x			
28						x				x		x			x	x	x	x						x		
29[a]							x		x	x															x	
+																										

[a] Special - sterilization process should be developed and qualified.

+ New product families that may be identified by the user.

6 Processing category

The medical devices included in a processing category should be based on product family and data that establish the efficiency of a specific sterilizer and its sterilization process for the processing category.

Medical devices of widely different attributes combined in the same processing category can cause an increase in the predicted steam penetration resistance. Based on the design of the individual instruments, the penetration resistance for the general orthopaedic set described in B.4 would be e2. However, due to the sterile barrier system, high total weight of the set, condensate collection, unpredictable air retention and susceptibility to an increase in air leakage into the sterilizer chamber or to the non-condensable gases contained in the steam, the steam penetration resistance for the general orthopaedic set is estimated as e5. The effect on the efficiency of the sterilization process from such combinations and changes should be known for each item contained in the processing category.

One example of how to designate a processing category for a number of procedure sets is illustrated in Annex D.

7 Sterilization process parameters

The maximum values for the process parameters a medical device can be safely exposed to during a moist heat sterilization process should not exceed those specified by the medical device manufacturer (see Annex A).

8 Additional considerations

8.1 Services

Variations in the quality of the services used during the delivery of a sterilization process can affect the efficiency of the sterilization process. Variations can also affect steam penetration resistance, levels of contaminants and the shelf life of some of the medical devices subjected to the sterilization process. The quality of the steam service should be as described in ISO/TS 17665-2:2009, A.11.2 and Table A.2.

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8.2 Process selection

A sterilization process consists of a number of prescribed stages carried out in a controlled sequence. The process variables and process parameters for each stage will define the type of medical device, processing category and load configuration that can be sterilized. The first stage will be designed to ensure that for a range of processing categories and load configurations, specified parts of each medical device will be sterile after exposure in stage two of the sterilization process. Returning to atmospheric conditions for use is carried out in the third stage.

In health care facilities, most medical devices are sterilized by saturated steam and the three stages of a sterilization process are, sequentially, air removal, sterilizing and drying. The design for the air removal stage will be based on the ease and way in which air can be removed from the surfaces of each medical device in the sterilization load. A simple air removal system will be passive and rely on gravity displacement of air resulting from the different densities of air and steam. This type of air removal system is unsuitable if air can be trapped, such as in a packaging system or a lumen. The alternative to gravity air removal is active air removal. Active air removal is achieved by using steam, vacuum pump or pressurized water as a power source to generate a series of pressure changes which can be below atmospheric pressure, above atmospheric pressure, or a combination of both. Upper and lower pressure levels, the number of changes and the characteristics of each change will be based on the type of medical device, the steam penetration resistance (see Table 6) and its processing category. Air removal should ensure residual air in the sterilizer chamber and on the surfaces of the sterilizer load is insufficient to affect the efficiency of sterilization.

Air leakage into the sterilizer chamber and non-condensable gases in the steam will adversely affect the efficacy of the air removal stage. It can also be adversely affected if medical devices of widely differing conductivity and/or weight are included in the same processing category.

Stage two will start at a specified minimum sterilizing temperature and exposure at this temperature should be the minimum specified for the holding time. Additional exposure to allow for temperature equilibration may be required when a high weight medical device is to be sterilized.

Stage three will be designed such that after the completion of drying, (normally by vacuum), filtered air will restore the pressure in the sterilizer chamber to atmospheric pressure. The duration of the drying stage will depend on the presentation and weight of each item of the sterilization load.

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Annex A
(informative)

Process parameters

A.1 The critical process variables for a moist heat sterilization process are temperature, time and presence of moisture (see ISO 17665-1). In order for a satisfactory process to be engineered other process parameters will need to be considered such as pressure, rates of pressure and temperature change and dwell times.

A.2 A medical device should not be exposed to process parameters that can adversely affect functional efficiency, therapeutic value and shelf life.

A.3 Process parameters used to ensure that a minimum sterility assurance is routinely obtained may be determined from either a parametric or a biological approach as described in ISO/TS 17665-2:2009, Annexes A and B respectively. Determining a process based on product bioburden considerations is discussed in ISO 17665-1, 7.3 and 8.5.

A.4 The tests described in ISO/TS 17665-2, Annex A, are prescribed for a parametric approach and are used to verify a minimum performance for a specific sterilizer. The data from these tests are used to establish the process parameters listed in A.1 and A.2 and to confirm that air and non-condensable gas remaining in a test load after the completion of the air removal stage will be insufficient to prevent the presence of saturated steam on all the surfaces of the test piece, including concealed surfaces that are open to the sterilizer chamber. The test piece and the performance requirements for these tests represent a high steam penetration resistance (see Table 6). Figure A.1 illustrates a temperature profile for the small load test (see ISO/TS 17665-2, Annex A).The difference in temperature between S_1 and S_2 can be used to judge the presence of saturated steam.

If the sterilization process and the process parameters identified from these tests are to be used to sterilize a medical device with a higher steam penetration resistance then data should be available to justify this decision. The rationale for this decision should be documented.

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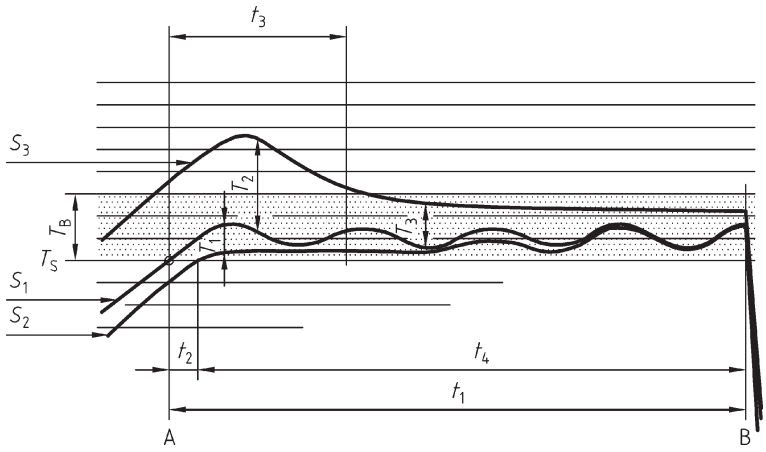

Key

A start of plateau period
B end of plateau period
T_s sterilization temperature
T_B sterilization temperature band
S_1 reference point
S_2 centre of test piece
S_3 50mm above test piece
T_1 maximum difference
T_2 maximum difference – first 60s
T_3 maximum difference – after 60s
t_1 plateau period
t_2 equilibration time
t_3 60s
t_4 holding time

Figure A.1 — Performance requirements: Small load test

A.5 Medical devices that have similar steam penetration resistance but which are characterized by attributes that are widely different may require exposure to dissimilar process parameters. If they are to be included in the same processing category such as in a procedure set, process parameters according to A.1 and A.2 should be verified.

A.6 While steam condensate remaining within a sterile barrier system may be used to identify a failure of the sterilization process, it may also be indicative of additive influence on steam penetration resistance. One or a combination of the following can be the cause:

— sterilizer chamber architecture;

— design and materials used to manufacture the sterile barrier system;

— load configuration;

— combination of high and low weight medical devices;

— water contained in the steam;

— operating cycle.

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