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World Federation for Hospital Sterilisation Sciences

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Schweizerische Gesellschaft für Sterilgutversorgung
Société Suisse de Stérilisation Hospitalière
Società Svizzera di Sterilizzazione Ospedaliera

PCD
State of the art

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What will be discussed:

- Definitions of PCD by international ISO standards
  - General requirements
  - Specific sterilization « process » standards

  Understanding what are/are not PCDs, according to standards
- When should they be used ?
- Summary and questions

1. PCDs and international standards

Definition of PCD according to ISO 11139

Sterilization of healthcare products — Vocabulary - terms used in sterilization and related equipment and process standards

- **ISO 11139: 2018**

Process Challenge Device - PCD

“Item providing a defined resistance to a cleaning, disinfection, or sterilization process and used to assess performance of the process ”

A broad definition

- **ISO 11139: 2006**

Process Challenge Device - PCD

“Item providing a defined resistance to a sterilization process and used to assess performance of the process ”

About the definition of ISO 11139 (2018)

- Cleaning and disinfection are included in the ISO 11139 (2018) definition of PCD,
- But …. the acronym PCD is not used in practice and by cleaning and disinfection standards.
- ISO 15883 talks about “representative device”.
- “surrogate device”* is used in 15883-5 (AER) for standardized test devices of annex H.

* **Surrogate device**
<endoscope> item designed to represent construction elements of endoscope specific characteristics affecting the flow conditions in endoscope channels

About the ISO 11139 definition …

- The definition of PCD highlights the word “process” i.e. applies to the verification of process performance (implemented by the health care facility),
- The PCD is more than a tool controlling that the sterilizer equipment works correctly, (this control may however be part of the process verification).

> ISO 11139 gives a definition of « processing » which may be useful:
> ***Processing*** *« Preparation of medical devices activity including cleaning, disinfection and sterilization to prepare a new or used healthcare product for its intended use »*
> « product » to be sterilized, means « process », hence entering the domain of ISO process sterilization (and outside the scope of EN sterilization equipment standards)

To be reminded:

ISO 17664-1:2021 - Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices

- 4.1 The medical device manufacturer shall validate each process that is identified in the information supplied with the medical device. Validation shall demonstrate that each process is suitable for processing of the medical device to ensure the device is suitable for its intended purposes.
- 4.2 The medical device manufacturer shall have objective evidence available that validation of the processing procedures has been undertaken to confirm that the specific medical device will be clean, disinfected and/or sterilized when processed as directed.

ISO 14937 (2009)

Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development,validation and routine control of a sterilization process for medical devices

- Standard applicable to all sterilization technologies which have not or not yet a dedicated standard.
- Also the “construction guide” for all sterilization standards (table of content and basic principles)
- ISO 14937 (2009) use PCD definition of ISO 11139 (2018)

> ***PCD**: Item designed to constitute a defined resistance to a sterilization process and used to assess performance of the process*

ISO 14937 (2009)

9 Validation

The purpose of validation is to demonstrate that the sterilization process established in the process definition (see Clause 8) can be delivered effectively and reproducibly to the sterilization load. Validation consists of a number of identified stages: installation qualification (IQ), operational qualification (OQ) and **performance qualification (PQ)**.

- 9.4.5 Les **indicateurs biologiques** employés pendant la qualification de la performance microbiologique doivent être conformes à 8.3.
- 9.4.7 Si des **indicateurs chimiques** sont utilisés dans la qualification de la performance, ils doivent être conformes à 8.4.
- 9.4.9 Si des **PCD** sont utilisés dans la QP, ils doivent être conformes à 8.6.

10 Surveillance et contrôle de routine

Le but de la surveillance et du contrôle de routine est de démontrer que le procédé de stérilisation validé et spécifié a été appliqué au produit.

- 10.5 Si des **indicateurs biologiques** sont utilisés dans la surveillance de routine, ils doivent être conformes à 8.3 a) et b).
- 10.6 Si des **indicateurs chimiques** sont utilisés dans la surveillance de routine, ils doivent être conformes à 8.4.
- 10.7 Si des **PCD** sont utilisés dans la surveillance et le contrôle de routine, ils doivent être conformes à 8.6.

8 Définition du procédé

Le but de cette activité est d'obtenir une spécification détaillée pour le procédé de stérilisation qui sera appliqué à un produit défini (voir article 7), sans compromettre ni la sécurité, ni la qualité, ni la performance de ce produit.

- **8.3** Si des **indicateurs biologiques** sont utilisés dans le cadre de l'établissement du procédé de stérilisation, ils doivent
  a) être conformes à l'ISO 11138-1 et à toutes parties ultérieures de l'ISO 11138 applicables au procédé de stérilisation,
  b) se révéler résistants à l'agent stérilisant par rapport à la charge biologique du produit à stériliser, et
  c) être placés dans le produit à des positions déterminées comme étant celles où les conditions de stérilisation sont les plus difficiles à atteindre, soit dans un dispositif d'épreuve de procédé (PCD)
- **8.4** Si des **indicateurs chimiques** sont utilisés pour établir le procédé de stérilisation, ils doivent être conformes à l'ISO 11140-1 et à toutes parties ultérieures de l'ISO 11140 applicables au procédé. Les indicateurs chimiques doivent être placés dans le produit à des positions déterminées comme étant celles où les conditions de stérilisation sont les plus difficiles à atteindre, soit dans un PCD.
- **8.6** Si des **PCD** sont utilisés dans l'établissement du procédé de stérilisation, **leur pertinence doit être déterminée. Les PCD doivent constituer une épreuve équivalente ou supérieure à celle utilisée à la position déterminée comme étant celle où les conditions de stérilisation sont les plus difficiles à atteindre.**

Differences health care facility vs industry (simplified)

Health care facilities

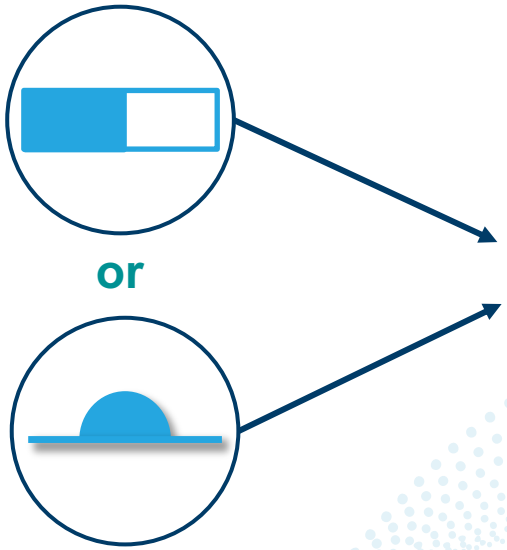
- Heterogeneous load
- Level of contamination not under controlled and variable according to DMs
- Overkill: 6 log of the most resistant germ

Medical device Industry

- Homogeneous load
- Known and controlled contamination level
- Overkill or most pertinent germ and adapted biological load

PCD for ISO 14937 – Health care facilities

CI or BI

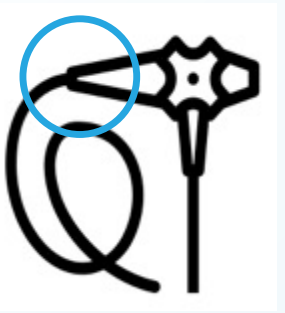


PCD

Challenge equivalent to or greater

≥

Than the position in product[1] where it has been determined that sterilizing conditions[2] are most difficult to achieve



1. In pratice the most challenging device in product family
2. For health care facilities, ≥ 6 Log of highly resistant spores according to overkill concept

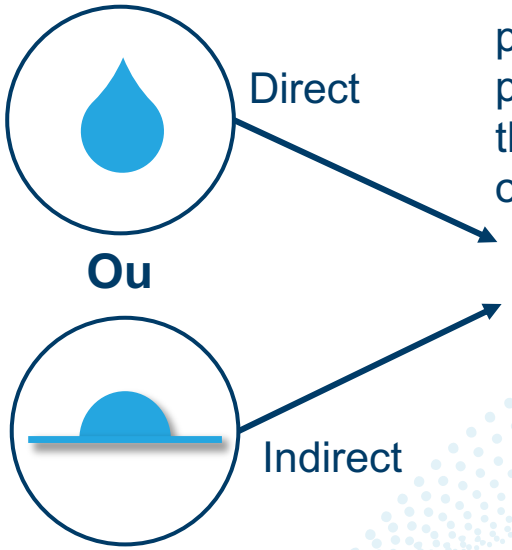
ISO 11135: 2014

Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices

- ISO 11135 (2014) uses the ISO 11139 (2006 definition of PCD (same as ISO 14937) and adds 2 notes:
  - For the purpose of this International Standard, a PCD can be **product, simulated product or other device that is inoculated** directly or indirectly. See 7.1.6 and D.7.1.6.
  - In this International Standard, a distinction is made between an internal PCD and an external PCD. An internal PCD is used to demonstrate that the required product SAL is achieved. A PCD located within the confines of the product or product shipper case is an internal PCD, whereas a PCD located between shipper cases or on the exterior surfaces of the load is an external PCD. An external PCD is an item designed to be used for microbiological monitoring of routine production cycles

PCD for ISO 11135

IB ou inoculum



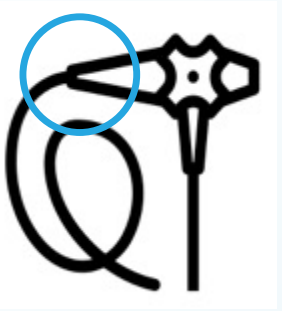
PCD

product, simulated product or other device that is inoculated directly or indirectly

Challenge equivalent to or greater

≥

Than the position in product[1] where it has been determined that sterilizing conditions[2] are most difficult to achieve



External PCD

Internal PCD
Required for product SAL qualification

1. In pratice the most challenging device in product family
2. For health care facilities, ≥ 6 Log of highly resistant spores according to overkill concept

ISO/DIS 22441

Sterilization of health care products — Low temperature vaporized hydrogen peroxide — Requirements for the development, validation and routine control of a sterilization process for medical devices

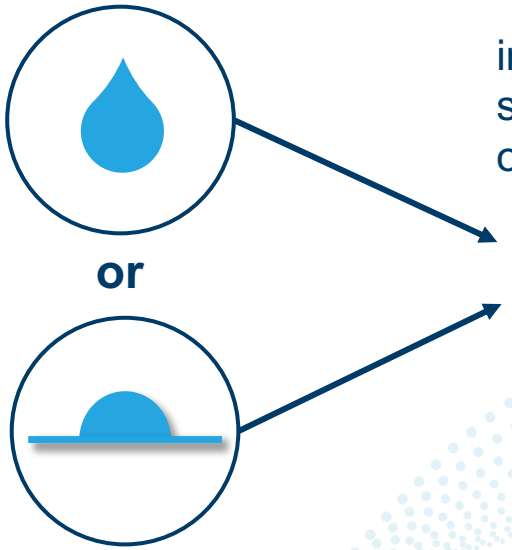
- ISO/DIS 22441 uses the definition of ISO 11139 (2018) and adds a note inspired by ISO 11135
  - For the purpose of this document PCD means an inoculated product, a simulation of a product or a test device.
- In addition to this, ISO 22441 adds an indication also found in ISO 11135
  - 8.6 If chemical indicators are used as part of the establishment of the sterilization process, they shall:

    c) not be used as the sole means of establishing the sterilization process;

    d) not be used as an indicator that the required SAL has been achieved.

PCD for ISO 22441 – Health care facilities

BI or inoculum



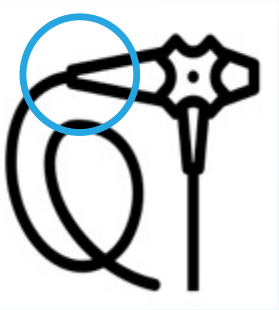
PCD

inoculated product, a simulation of a product or a test device

Challenge equivalent to or greater

≥

Than the position in product[1] where it has been determined that sterilizing conditions[2] are most difficult to achieve



1. In pratice the most challenging device in product family
2. For health care facilities, ≥ 6 Log of highly resistant spores according to overkill concept

ISO 17665 and draft

Sterilization of health care product— Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for médical devices (2006)
Sterilization of health care products — Moist heat — Part 2: Guidance on the application of ISO 17665-1

- ISO 17665 (2006) uses the definition of ISO 11139 (2006) but the revision in progress (soon entering DIS) adds a note which substantially differ from the notes to PCD definition of ISO 11135 and ISO/DIS 22441
  - For the purpose of this document, the item can be product, simulated product or other reference device. The item can contain a physical, biological or chemical indicator

ISO 17665 (draft)

- ISO 17665 has specific requirement worded as follows in the draft in progress
  - 10.2 The operational status of the equipment shall be verified by evidence from the following periodic tests…..
    - d) a steam penetration test using a defined test load which shall be conducted using devices independent of the sterilizer and the sterilizer control.
    - NOTE 2 The steam penetration test comes in many forms including Bowie and Dick tests and hollow process challenge devices both of which can contain an indicator.

- ISO 17665 (draft) refers like other standards to product family concept. For example in validation paragraphe,
  - 9.5 Review and approval of validation
    - i) the PCD and the product family(ies) for which it is relevant

EN 867-5[1] and ISO 11140-6[2] (draft)

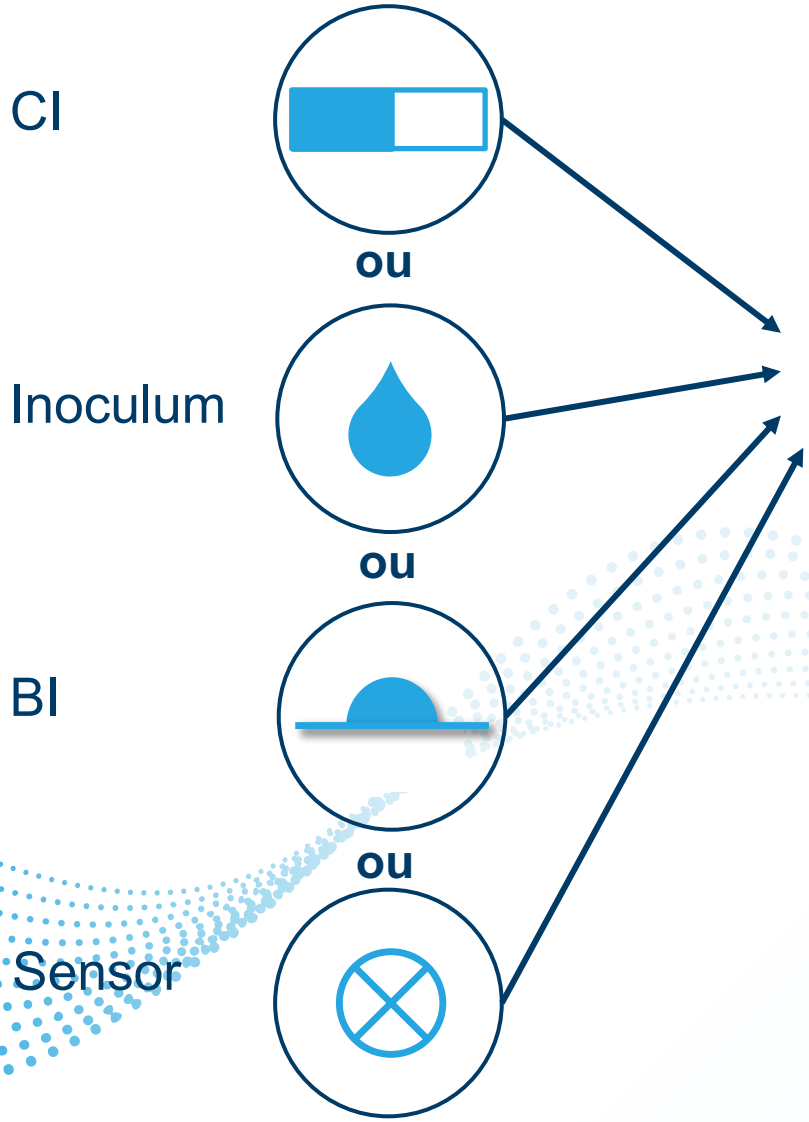
1. Non-biological systems for use in sterilizers - Part 5: Specification for indicator systems and process challenge devices for use in performance testing for small sterilizers Type B and Type S*
2. ISO/CD 11140-6 sterilization of health care products – chemical indicators- part 6: Class 2 indicators and process challenge devices for use in performance testing of steam sterilizer

- It was decided that the EN 867-5 had to be revised to correct faults in this document and that it would be become an ISO standards. ISO 11140-6 (draft) is intended for manufacturers and specifies the requirements for chemical indicators and process challenge devices used as steam penetration test to monitor type B cycles and some type S cycles of small steam sterilizers conforming to EN 13060

- The scope paragraph of 11140-6 says ….The suitability of the hollow and porous devices described in this document as surrogate devices for hollow and porous medical devices used in health care facilities is not substantiated

* EN 867-5 is also used for type testing (test by manufacturers) of large steam sterilizers complying to EN 285.

PCD – ISO/CD 17665



PCD

Product or simulated product or other reference device

≥

PCD ?

B&D Porous load
ISO 11140-2 or 3, 4 / CI or sensors

≠

Hollow load
EN 867-5 / ISO/DIS 11140-6

?

Standardized AAMI16 towels pack
BI and CI

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2. Summary and questions

Point of view and questions of the hospital user

	Steam sterilization ISO 17665	**H_2O_2 / ETO sterilization** ISO 14937- ISO 1135- ISO/DIS 22441
Control of cycle parameters	Criteria n°1 for cycle validation in routine and PQ (sensors in load at different locations)	Criteria N°1 for cycle validation in routine and PQ
PCD With CI	Lack of information demonstrating their interest in the hospital	NA
PCD with BI (BI PCD)	Interest not demonstrated in hospital*	Pertinent
Penetration test	Daily and in QP B&D porous filler and its equivalent for hollow load are not PCDs Added value of the shaped load test?	?

* Required by some national regulations

Let's continue the discussion with a WFHSS working group !

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