27th WFHSS CONGRESS - 2026 -

BELGRADE

21ST - 24TH OCTOBER 2026

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World Federation for Hospital Sterilisation Sciences

Adapt to Adopt
Interpretation of ISO 22 441 by Three French-Speaking Sterilization Associations in Belgium, France, and Switzerland

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Two days 2025
April
Southern France

ASTER: Isabelle, Sandrine, Sigurd
SF2S: Christophe, Marc, Hervé
SSSH: Frédy, Hervé, Nicolas

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Build together (1)

Identify areas of convergence among the three associations:

- **Standards and National regulations**
- **Recommendations from current practices and literature**
- **Test acceptance criteria**
- **Best Cost / Benefit / Risk ratio for the users**

- ***SF2S Day of March 20, 2025***
- ***Exchanges with KOL in the field of VH_2O_2 sterilization***

Build together (2)

Red Insert:This symbol indicates that this is a requirement—Mandatory requirement
For example, normative annexes A - D of ISO 22 441

Blue Insert: This symbol indicates that this is a recommendation—Advice, Caution
For example, Informative Annexes E - K of ISO 22 441

Example: **The VH2O2 sterilization process must be validated, considering the regulations in each country.**

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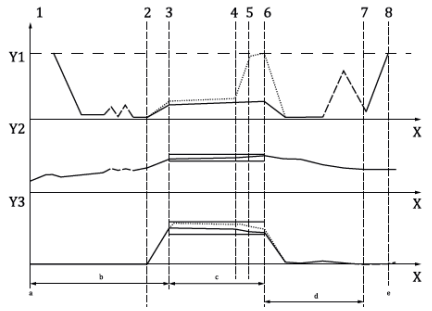
Keys points

SN ISO 22441:2024 en for committee internal use only
ISO 22441:2022(E)

Annex F
(informative)

Schematic example of a VH2O2 sterilization cycle



Key

Y1	pressure	1	start of the sterilization cycle
Y2	temperature	2	start of exposure phase
Y3	concentration	3	start of holding time
X	time	4	start of air/inert gas injection pulse(s) (if applicable)
		5	end of air/inert gas injection pulse(s) (if applicable)
a	start of cycle	6	end of holding time and start of purging stage
b	conditioning stage	7	end of purging stage and start of air admission
c	holding time	8	"cycle complete"
d	purging stage		
e	end of cycle		

Figure F.1 — Schematic example of a VH2O2 sterilization cycle conforming to EN 17180

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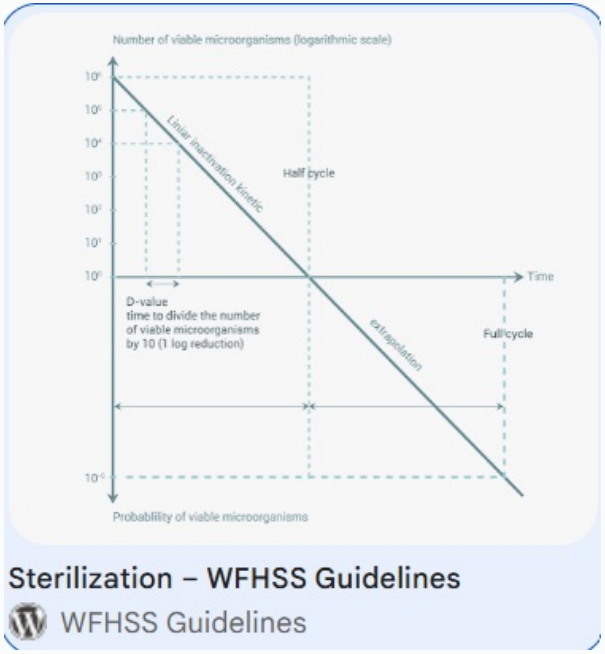
Overkill method
SAL
Half-Cycle (Annex D ISO 22 441)



Common presentation of validation and routine controls guidelines

- Abbreviations
- Definitions according to EN ISO 11 139
- Legal and Regulatory frameworks (depending on the country)
- Responsibilities
- Validation of the sterilization process carried out within the framework of a QMS
- Qualified professionals
- Knowledge of equipment

*Mandatory

The person* conducting the performance qualifications should be independent of the company that manufactures or sells VH_2O_2 sterilizers

Point of vigilance

Facilities (CSSDs) must ensure the qualification and experience of peoples performing technical measurement, for instance through an internal or external service agreement, or by using a specification document that outlines the services to be carried out.

VH_2O_2 sterilization process (1)

The process parameters, along with their tolerances, must be specified (data must be provided by the sterilizer manufacturer) — See Appendix 2

- Description of operating cycles (including vacuum test cycle if applicable), specifying for each all of phases of sterilization process
- Description of process parameters, including their tolerances (typical diagram and numerical values for each program)
- Time intervals and set points
- Temperature (of the load, chamber and vaporizer)
- VH_2O_2 concentration (measured directly or indirectly)
- Pressure
- Maximum dynamic pressure values (maximum rate of pressure change (pr EN 17180))

VH_2O_2 sterilization process (2)

- Specification of the sterilant and the means to generate and deliver the sterilizing agent to the chamber
- Restrictions regarding the medical devices to be sterilized and load configuration for each operating cycle (configuration, temperature, size, mass, materials components, geometry, packaging system, temperature and moisture for any load preconditioning requirements)
- Approved List of medical devices validated (by manufacturer of medical device and sterilizer)
- Location of CI and BI when used
- Safety Data Sheet

Characterization of VH_2O_2

The user must request the manufacturer to provide:

- **Physical description of the sterilizer, with all necessary accessories**
- ***Temperature and ventilation conditions of the operating area***
- **Locations of the reference measurement point(s) of sensors and the sterilizer's indication and recording instruments**
- **Safety features (protection of people and environment)**
- **Process residues level (to ensure they are below the specified limits identified in the health risk assessment)**
- **Description of the IMS (if existing)**

Product definition

- Concept of product family taking in account both manufacturer's medical devices and sterilizer instructions (What?)
- Definition of product families and testing the most critical aspect (Why?)

- *Washing, disinfection and packaging must be validated beforehand by the user*

- If it is planned to use a PCD, it must correspond to the most restrictive medical device for the operating cycle

Definition of the Process (1) CI / BI

BIs must be used for validation (OQ and PQ) and during performance requalification.

The use of BIs is optional for routine testing and load releases.

CIs must be used for validation (OQ and PQ) and performance requalification
The use of CIs is optional for routine monitoring and load release



CIs may be used for validation and/or during routine controls

Definition of the Process (2) PCD

- **Optional use**
- **Number depends on the usable chamber space**
- **If used during validation or routinely, justify and document the relevance of the PCD (User AND PCD manufacturer's attestation: sterility tests according to EN ISO 11 737-2)**

- ***If 3 PCD's are used routinely, then 3 PCD's used routinely AND 3 PCD's from the provider to ensure validation if the PCD's are different***

Definition of the Process (3)

The BI, CI, and PCD used for validation must be the same as those used in routine operations.
When these are not used in routine operations, the validation organization must provide the corresponding certificates of conformity.

It is recommended to use PCD with BI or CI, rather than BI or CI alone

Validation steps (1)

- **Documented process**
- **Contract** between user and manufacturer of the sterilizer for IQ and OQ
- User approves the IQ and OQ protocol and reports
- **Users defines the PQ**: Objectives, protocols and documents, stakeholders, medical devices to sterilize

The health care facility must approve the IQ/OQ/PQ validation reports

Validation steps (2)

- **Establishment of the validation plan** between the parties concerned for the defined VH_2O_2 sterilization processes (packaging, programs, medical devices, critical load, dates of reception of the final reports, …)
- The use of a PCD cannot replace a real-load medical devices during the PQ
- Completion of the validation: IQ and OQ by the sterilizer manufacturer
- **PQ by the sterilizer manufacturer and/or the third-party service provider and/or the user**
- *Preparation of **the provisional report** by the qualification body*

Validation steps (3)

- **Approval of the provisional report** by the responsible pharmacist or user
- **Preparation of the final report** by the sterilizer manufacturer and/or the third-party service provider and/or the user
- **Approval the final report** by the responsible pharmacist or user
- **Definition of process monitoring parameters and routine controls**
- **Requalification planning**

IQ (1)

- Performed during equipment installation and approved by the manufacturer and the designated facility manager :

Technical / Biomedical service and pharmacist  

- Location of the sterilizer and its accessories
- Precautions and special arrangements regarding the safety of the equipment, the environment (appropriate air treatment, monitoring of room temperature, storage conditions for sterilant) and CSSD users
- Occupational exposure limit for hydrogen peroxide

IQ (2)

- **Services required and verified:** i.e. power supply, compressed air, computer connection
- **Characterization of the sterilizer:** i.e. brand, reference, model, CE marking, compliance with applicable standards, serail number, overall sizes and usable chamber space
- **Operating procedure containing at a minimum**:
  - Operating instructions
  - Alarms and malfunctions
  - Maintenance and calibration instructions, and their frequencies
  - Contact persons for technical support
  - Definition of the reduced cycle (i.e: half-cycle) used during PQ, specifying when and how the cycle should be interrupted
- Leak test, *if the program exists*

A single non-compliant item renders the IQ invalid. The non-compliant item, or any non-compliant items, must be corrected

OQ (1)

OQ can only be carried out once the IQ results are available, compliant and approved

- ❑ Complete during sterilizer installation
- ❑ Partial, possibly during the RPQ *(If calibration of measuring instruments for example)*

- ➢ **Calibration of all measuring instruments**: pressure and temperature sensors in accordance with specifications of the sterilizer manufacturer
- ➢ **Validity of certificates** for measuring instruments used
- ➢ **Basic safety precautions**: verify the operation of all alarms (threshold and display)
- ➢ Basic operating control and monitoring system including verification of H_2O_2 supply systems (references, batch, expiry date)

OQ (2)

- **Performance physical parameters** with onboard temperature and pressure sensors

- With a **low load** (**one unit** of the smallest medical device package and sterilized by the user) **AND**
- With a **full charge**

A complete cycle to demonstrate that:

- The temperature, pressure and H_2O_2 concentration do not exceed the limit values specified by the manufacturer throughout the sterilization cycle
- Pressure variations do not damage the packaging or the medical device (visual inspection)

The full load, as determined for each cycle used, must be representative of the maximum loads routinely applied

OQ (3)

- **Supply / consumption of sterilant**

During the full OQ, the results of physical and/or microbiological performance tests at low and full loads are the responsibility of the sterilizer manufacturer. Demonstration that the temperature and the pressure supply conditions guarantee microbiological lethality is achieved, is required

- **Ambient monitoring tests (EN IEC 61 010 – 2 – 040): maximum H_2O_2 emission**

- **Load dryness test:** no visible residue should be found on the load (droplet of H_2O_2 or whitish dry residue)

A single non-compliant item renders the OQ invalid.
The non-compliant item, or any non-compliant items, must be corrected

PQ (1)

PQ can only be carried out once the IQ and OQ results are available, compliant and approved

Full cycles or reduced cycles must include the medical devices specified during the critical load

- A vacuum or leak test, if the program exists
- **A minimum of three consecutive reduced cycle** (e.g. half-cycle) **of each program** are required to verify the inactivation of the BI's
- And at least **one complete cycle for each program used**, to have reference records than can be used for routine release

PQ (2)

- **The sequence of PQ cycles or half-cycles must ensure that the loads returned to routine environmental conditions (temperature and dryness of the medical device).** If the loads are sequenced, the medical devices should be cooled between each cycle to reproduce routine conditions

Full load OQ cycles are not usable for PQ

- **The load must contain packaged medical device, representative of the one which is routinely used**
- **The medical device considered the most difficult to sterilize must be included in the test load composition for each program used:** For example, for a program for flexible endoscopes, use an endoscope with specifications close to the limits set by the sterilizer manufacturer (number, diameters and lengths of channels, materials and mass)

The reasons for the choice regarding the loads that are most difficult to sterilize must be documented

PQ (3)

- **Medical Device packaging compatible**
- **Loading plan:** the contents of the sterilizer must be documented (full written description or picture of each load) The orientation and position of the medical device(s) within the load must be indicated.
- **Cycle recording data conforming to the specifications (Set points and tolerances) :** temperature and pressure sensors of the sterilizer and independent sensors used for the PQ
- **Results of the BI's**
- **Results of the type 1 CI's**
- **Results of CI's from another** type with at least 2 criticals parameters if used according to the manufacturer's instructions in a complete cycle
- **Visual checks of the integrity of packaging** (seals, residues or droplets, stain free, ...)

Validation report

- Description materials and methods
- Results of the controls for each step of the validation process
- All valid calibration certificates for the measuring equipment used
- Must be:
  - ✓ Understood
  - ✓ Verified
  - ✓ Approved by the person designated by the user as responsible of the validation

This person is different from the one who takes the measurements

The person who carried out the measurements must produce a provisional summary report stating that the equipment can be used in accordance with the defined procedures

Complete IQ/OQ/PQ validation records must be documented and archived in accordance with current regulations 16 years

Requalification Performance (1)

All or part of IQ, OQ, PQ performed after certain events such as major repair or repositioning, or **regularly**

- Equipment: replacement or modification of a part)
- Process: new control software, new program
- New medical device “without family”
- Packaging

The RPQ is carried out at least once a year following a full service of the equipment in accordance with the manufacturer’s recommendations.

This must be documented and recorded

Requalification Performance (2)

Contains at a minimum:

- A vacuum or leak test, if the program exists
- **Three reduced cycles** (i.e.half cycle) **consecutive for the program defined** to verify the inactivation of the BI's
- **A complete cycle for the same program**, to have reference records that can be used for routine load release

It is recommended to change the program every year

Inspections for each load (checks) (1)

Vacuum or Leak test, if used

- Verify the program used
- Parameters obtained compared to reference parameters (validation)
- Parameters obtained from the IMS compared to reference parameters (validation)
- Compliance of the CI's
  - Type 1
  - Multiparametric (minimum 1) if used
- Packaging integrity
- Packaging dryness (absence of H_2O_2 droplets)

Inspections for each load (checks) (2)

If the sterilizer does not have an IMS, the routine use of 1 BI per load is mandatory

CI'S or BI's are preferably used with a PCD, which must be specified and whose relevance must be determined

The sterilized load is considered non-compliant whenever the results are not satisfactory or there is a doubt about a result
In this case, the load must not ne released

An analysis of the causes must then be carried out and corrective measures must be taken

Appendix: test sensors and BI's (1)

- **Mapping of the locations** of measurement test sensors and BI's must be carried out
- One or more test sensors are usually **positioned as close as possible to the sensors of the sterilizer chamber**
- BI can be used with a PCD
- The working group proposes **an adjustment of the number of temperature sensors and BI's to be used** for sterilizers whose usable chamber space corresponds to the equipment commonly used in health care facilities

Appendix: test sensors and BI's (2)

Volume (L)	Temperature sensor	BI
< 100	3	3
100-250*	At least 4	4
100-1000	12	6
> 1000	24	12

For usable chamber space from 100 to 250 liters, each sensor and BI can be positioned as follows:

- Front door of the sterilizer
- Rear door or back of the sterilizer
- Near the sterilizer's temperature sensor
- In the center of the load

Appendix: External Measurement Instrumentation

- **Pressure:** 1 measurement per second is recommended

- **Temperature:** Every 2 seconds or more frequently

- **Measurement of concentration of sterilizing agent:**

A quantitative assessment of the correlation between the concentration measurement result for the sterilizing agent and the microbiological performance must be guaranteed

It is not possible at present to formulate requirements concerning these measurement systems

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Thank you for your attention

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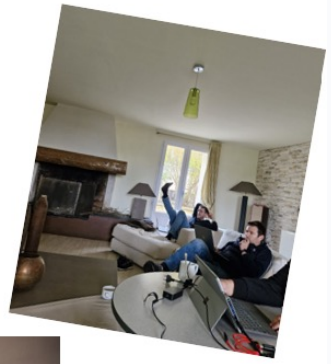



Big Hugs to all my friends







